



**Project VALOR  
Informed Consent Statement**

Principal investigator: Terence M. Keane, PhD

**INTRODUCTION**

This is a research study about the effects of military experience and health care access and utilization among veterans. Primarily we are interested in the development and course of PTSD (post-traumatic stress disorder), and other difficulties that may have resulted from your military service. We would like to ask for your help by continuing to participate in this study, whether or not you feel like you have any of those symptoms. In total, 1649 veterans are expected to participate in this study. This study is being conducted by the VA Boston Healthcare System and New England Research Institutes with funding from the Department of Defense.

**DESCRIPTION OF THE STUDY AND STUDY PROCEDURES**

This wave of the project will take place over the next 4 years and we would like to collect more information from you 3 more times. If you decide to participate, the study team will access your electronic VA medical record over the course of the study in order to obtain information about your past, present, and future use of VA health services. The study team will access your medical record when you first enroll in the study as well as 3 additional times during the 4 years of the study.

If you decide to enroll in the study, you will be asked to complete an online questionnaire 3 times. Similar to the questionnaire you filled out last time, the surveys will ask about your background, day-to-day life, war experiences, sleep habits, emotions, and your use of health services.

You will also be asked to complete two more telephone interviews, similar to the one you already completed. The interviews will take place about 2 years apart, over the phone, in calls lasting about 60 minutes. A doctoral-level clinician from the VA Boston Healthcare System will administer an interview regarding your psychological health and possible impairment you experience in your social and occupational life, as well as ask questions about your use of health services. All interview and questionnaire data will be kept confidential. If you complete all the parts of this study, you will be paid \$325 for your time and participation in the study.

**If you gave permission during the consent phone call for your interview to be recorded:** The interview will be recorded in digital audio format for later review and will be password protected and archived in a secure location under the supervision of Dr. Brian Marx at the VA Boston. It will only be reviewed by approved study staff for research purposes. Because the interview will be conducted over the phone and we might not get all important information in writing, we would like to retain the tapes for 5 years after your interview date.

**If you did not give your permission during the consent phone call for your interview to be recorded:** The interview will not be recorded.

**POSSIBLE RISKS AND DISCOMFORTS**

Answering questions about military experiences and current psychological and personal life problems during the interview or while taking the surveys may be uncomfortable or unpleasant for you. It is



possible that you could experience increased distress as a result of thinking of past experiences and current life circumstances. We will assess how you are feeling throughout the procedure. Should you become distressed, a clinical psychologist will be available to talk to you by phone at any point during or after the study. Project staff will also be able to provide you with an appropriate mental health referral should you request one. Also, you may experience a previously unknown risk or side effect from participating in this study. If this occurs please notify the Co-Investigator Dr. Michelle Bovin at the VA Boston at (857) 364-4123 during normal business hours.

When completing the study surveys or interview, you may refuse to answer any question you do not feel comfortable answering. Your refusal will not affect your ability to receive benefits to which you are otherwise entitled. You may stop participation at any time during the study. You will not have to tell the study staff why you want to end your participation in the study.

### **POSSIBLE BENEFITS**

There are no known direct benefits to you for being in this study.

### **OTHER TREATMENT AVAILABLE**

This is not a treatment study and therefore, will not alter any treatment you are receiving at the VA.

### **USE OF RESEARCH AND CONFIDENTIALITY**

Information collected for the purpose of this research study will be kept confidential as required by law. The results of this study may be published for scientific purposes, but your records or identity will not be revealed unless required by law. Eventually the de-identified data from this study will be made available to qualified researchers in the academic community.

Information about you is protected in the following way. All identifying information will be password protected if stored electronically, and all information on paper will be stored in a locked cabinet in the Study Coordinator's office at the National Center for PTSD, VA Boston. Participants will be identified by participant numbers, not by name. Only the Study Coordinator and the Principal Investigator will have access to the locked and password protected information. One exception is that the Systems Administrator at the National Center for PTSD will also have access to the protected computer drive. All data containing identifiable information will be stored on a secure network drive and will never be transported outside of the VA; however de-identified data will be transferred outside of the VA Boston Healthcare System to the New England Research Institutes for data analysis.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).



You should understand that 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. This means you must actively protect your own privacy.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances: in the event that you report engaging in behavior that constitutes child abuse or elder abuse as defined by the Commonwealth of Massachusetts; or, you are deemed at immediate risk of suicide; or, you are deemed to be at risk for doing bodily harm to a specifically identifiable individual.

Your research records will be kept indefinitely. If and when the records are destroyed, all paper instruments will be shredded. All research information for this study that is maintained on electronic storage and memory devices (e.g., computers, laptops, CDs, audiotapes, etc.) will be destroyed in a manner in which it cannot be retrieved.

#### **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.

#### **COST TO PARTICIPANTS AND COMPENSATION**

A veteran subject will not be required to pay for medical care and services received as a participant in an approved VA research study. Some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services (including, but not limited to, dental services, supplies, medicines, orthopedic and prosthetic appliances, and domiciliary or nursing home care) provided by the VA that are not part of this research study.

You will be compensated \$325 in total for completing the 3 surveys and 2 interviews. You will be paid after each point of contact. During the first point of contact, you will be paid \$100 for completing the interview and online questionnaire. During the second point of contact, you will be paid \$75 for completing the questionnaire. Finally you will be paid \$150 during the third point of contact for completing the questionnaire and interview. If during the first and/ or third point of contact you only complete the questionnaire rather than both the questionnaire and interview, you will be compensated 1/2 the amount of the normal compensation for that time period.

You will be paid by checks made out to you, which can be cashed in multiple check-cashing institutions. These checks will be mailed to you. You consent to the release of personally identifiable information including your name and address to Hanscom Federal Credit Union and the Boston VA Research Institute, Inc. who will provide the administrative support for processing your compensation.



## **RIGHTS OF RECOURSE**

In the event that you are injured as a result of your being in this research study, you will receive medical care, including emergency treatment. This care or treatment is governed by federal law and VA policy. You would also have the right to file any legal action, as in any instance of alleged negligence.

## **STUDY MONITORING**

You consent to the access of your VA research and medical records that may identify you by persons approved for this purpose. Such access may be by the Human Studies Subcommittee of this hospital, the VA, other involved federal agencies, the Office for Human Research Protection (OHRP), the Government Accountability Office (GAO), and other national research oversight and accreditation organizations. You may expect the same confidentiality from these persons that is given to you by the Investigator and his/her research staff. Also, representatives from the US Army Medical Research and Materiel Command (USAMRMC) are eligible to review research records as part of their responsibility to ensure the protection of human subjects.

## **VOLUNTARY PARTICIPATION**

**I understand that my participation in this study is voluntary, that I do not have to take part in this study and that, if I do take part, I may withdraw from the study at any time. I also understand that, if I refuse to take part or if I decide to withdraw, I will not suffer any penalty, loss of rights, or loss of VA or other benefits that I have a right to receive.**

**I understand that if I have any medical questions about this research study, I can call Dr. Brian Marx at (857) 364-6071 during normal working hours (M-F, 9am-5pm EST). If I have any medical problems that might be related to this study I can call Dr. Michelle Bovin at (857) 364-4123 during normal business hours and after hours I can call the Medical Center operator at (617) 232-9500 and ask for the fellow on call or a psychiatry resident on call.**

**I understand that, if at any point during or after this study I have any questions about my rights as a research subject or I want to discuss problems, complaints, concerns, and questions about the research, obtain information, or offer input, I may contact the Research Compliance Officer at (857) 364-4182.**

