



October 14, 2008

Dear Guard Member:

You have been selected to take part in a study that is being conducted by the University Hospitals Case Medical Center in Cleveland, Ohio in cooperation with the University of Toledo, the University of Michigan, the Ohio National Guard, and sponsored by the Department of Defense. Please also find enclosed a letter of approval for the study from The Adjutant General, Major General Wayt of the Ohio National Guard.

The purpose of this study is to learn about the experiences of Guard Members, how these experiences may affect their lives over time, and what the factors are that improve how Guard Members cope with their military experiences. Guard Members who choose to participate will be compensated for their time.

Your name has been selected at random from a list of Guard Members to participate in this important study. If you are **not** interested in participating, please let us know by returning the enclosed reply form in the pre-addressed stamped envelope. If we do not hear from you by November 4, 2008 a research associate will call you to ask about participating in this study.

All individuals who participate will be interviewed by telephone. A small sub-group of the telephone survey group will also be invited to participate in an in-person interview.

The Telephone Interview – A national telephone survey company named Abt SRBI, Inc (SRBI) will be conducting the survey interviews by telephone. Each telephone interview will take up to **1 hour** and will be scheduled at a time that is convenient for you.

The In-Person Interview – If you are randomly selected to be part of this sub-group, study staff from the University Hospitals Case Medical Center or University of Toledo will complete interviews in-person at a location convenient to you. This interview takes about **2 to 3 hours**.

This study may potentially last up to 10 years, with re-interviews every year. If you choose to participate you are not required to participate for the entire duration of the study.

The following is an outline and description of the procedures that are involved with study participation:

Telephone Interviews:

Initiation of Study Participation: Personnel from SRBI will contact you at the number provided by the Ohio National Guard within a few weeks of receiving this letter if you have not declined to be

contacted about participating. At that time, personnel from SRBI will set up a time and date that is convenient for you to discuss study participation and complete your first telephone interview. You may be contacted at the same number or one provided by you. This call and subsequent calls are described below.

Study Calls: Interviewers will use research assessments and questionnaires to gather information and record your answers. You will be asked to provide information about your military experiences, life time exposure to traumatic events, use of medical and health services, family history, medical and psychiatric history, your date of birth, work history, and quality of life issues, such as limitations due to pain, and health and emotional concerns.

Study Call 1: This first call is your “baseline” interview. During the baseline interview, you will be asked many different questions about the above mentioned experiences. This “baseline” interview, and all following interviews, will take about 1 hour to complete.

Follow-up Calls: The process described above, including most of the same questions, will be repeated during each interview for the duration of the study. Interviews will take place each year, around the anniversary of your baseline interview, and after any deployment for up to 10 years regardless of whether or not your enlistment is current. If you are deployed, we will not attempt to complete interviews until you have returned. Post-deployment interviews will take place 90 to 180 days after your return.

If you are randomly selected to complete the In-Person Interview:

Initiation of Study Participation: If you have also been selected to participate in the in-person interviews, you will be invited by SRBI personnel at the time of your first telephone interview. You will be contacted by study personnel from University Hospitals Case Medical Center or University of Toledo to schedule a convenient time to meet to complete the first in-person interview. This visit and subsequent visits are described below. All in-person interviews will be completed at a convenient, neutral location decided on by you and the study staff. If you do not wish to complete the in-person survey, you may decline.

Study visits: In-person interviews will follow the same time line as the telephone interviews. Interviewers will use research assessments and questionnaires to gather information and record your answers. You will be asked to provide information about your military experiences, life time exposure to traumatic events, use of medical and health services, family history, medical and psychiatric history, your date of birth, work history, and quality of life issues, such as limitations due to pain, and health and emotional concerns.

Study Visit 1: This first visit is your “baseline” interview. During the baseline interview, you will be asked many different questions about the above-mentioned experiences. This “baseline” interview, and all following interviews, will take about 2 to 3 hours to complete.

Follow-up visits: The process described above, including most of the same questions, will be repeated during each interview for the duration of the study. Interviews will take place each year, around the anniversary of your baseline interview, and after any deployment for up to 10 years regardless of whether or not your enlistment is current. If you are deployed, we will not attempt to complete interviews until you have returned. Post-deployment interviews will take place 90 to 180 days after your return.

The following is a list of possible risks from participating in this study:

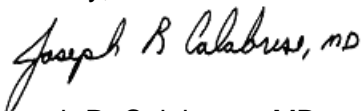
- Psychological discomfort, distress or worsening of symptoms during the interviews: You may find the study questions very difficult to answer or talk about. If you feel bad or distressed during the interview, you may stop the interview at any time. If you wish, study staff may also provide you with information about community resources and about the OHIOCARES network or put you in touch with a counselor.
- Fear of negative perception by military authorities if participation in the study is known: You may be worried that your peers will find out that you are in this study. While this study is being done with guidance from knowledgeable military and Veterans Administration staff and complete protection of your identity cannot be guaranteed, all allowable precautions have to been taken to help ensure that your identity will not be known and that the data collected will not be associated with your name or other identifying information. **All study participants will be assigned a unique ID # that will be used instead of your name on all study materials so that your name will not be directly linked to any study documents or data.** The only link between your name and study ID # will be kept in a locked database accessible only by authorized study personnel. All study records will be kept in a separate database, away from Ohio National Guard records, in a locked cabinet within a locked office at the data management center. **Military personnel will not have access to identifiable study data.** Therefore, data collection, information storage and all private knowledge that result from this study have no connection to your chain of command, benefits or military record. In addition to the above procedures a Certificate of Confidentiality has been obtained from the National Institute of Health (NIH) to help prevent forced disclosure of sensitive research information collected from study subjects. **All study procedures are voluntary.** Participation in, or withdrawal from this study will not affect your enlistment, benefits or military record in any way. You may withdraw from the study at any time. You may decline to answer any questions that make you uncomfortable.
- Physical Risks: There are no known physical risks to you for participating in this study. If you are hurt due to an unrelated event, contact your regular doctor. Should you be injured as a direct result of joining this research project, you will be provided medical care, at no cost to you, for that injury. You will not receive any payment for the injury, only medical care.

Participation in this survey is completely voluntary and choosing not to participate will have no impact on your status in the Guard, or benefits to which you may be entitled. If you choose not to participate, simply return the enclosed pre-addressed card or inform the research associate who contacts you and we will remove your name and number from our list. If you do choose to participate, you have the right to withdraw your participation in the study at any time with no impact on your status in the Guard or benefits to which you may be entitled.

We appreciate your time and consideration. If you have any questions or concerns about the study in general or the interview, please feel free to call the principal investigator, Dr Joseph Calabrese, at the study toll free number 1-866-60 ASK UH (1-866-602-7584), or visit the project website at www.SRBI.com\ONGStudy. If you have any specific questions about the interview or would like to schedule an appointment, you can call SRBI at their toll-free number 1-800-716-0940. Please specify that you are calling about the Ohio National Guard STUDY # 4182. If you prefer, you may choose to send a message by email to ONGStudy@srbi.com.

Thank you again for your help.

Sincerely,



Joseph R. Calabrese, MD
Principal Investigator
University Hospitals Case Medical Center
Case Western Reserve University



Marijo Tamburrino, MD
Co-Principal Investigator
University of Toledo

Enclosures

TAG letter
Reply Form and return envelope