Department of Veterans Affairs

RESEARCH CONSENT FORM

CHAI Neurocognitive Assessment

Version Date: May 19, 2017

Participant Name:_____ Date:_____

Title of Study: Coming Home from Afghanistan and Iraq (CHAI) Study Neurocognitive Assessment

Principal Investigator: Aaron Schneiderman, Ph.D. VA Facility: VHA PDHS, Washington, DC

INTRODUCTION

You are being invited to take part in a research study that is being funded by the Department of Veterans Affairs (VA). Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive.

Read the information below closely, and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part in this study, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

WHAT IS THE PURPOSE OF THIS RESEARCH?

The purpose of the Coming Home from Afghanistan and Iraq (CHAI) Study is to determine the effect of military service, deployment and combat on the health and well-being of Operation Enduring Freedom (OEF) and Operation Iraqi Freedom (OIF)/Operation New Dawn (OND) Veterans, and their adolescent children. The information collected by the study will be used to improve the VA's understanding of the long-term health consequences of military service, deployment and combat for post-9/11 Veterans.

WHO IS CONDUCTING THIS RESEARCH AND WHO IS SPONSORING IT?

The U.S. Department of Veterans Affairs, Veterans Health Administration (VHA) is conducting this research. The study is funded by the VHA Post-Deployment Health Service, and being implemented by Abt Associates, Inc. under contract VA 777-13-F-0464.

WHY ARE HUMAN SUBJECTS BEING ASKED TO TAKE PART IN THE STUDY

The main component of the CHAI Study is the survey of post-9/11 Veterans that you completed. The purpose of the Neurocognitive Assessment Study is to help the VA understand differences in cognitive functioning that may be associated with deployment and combat among Veterans with and without a history of harm or injury. Neurocognitive testing, also known as neuropsychological testing evaluates cognitive status in specific neurologic domains such as,

memory, attention, problem solving, language, visuospatial, processing speed motor, and emotion. Whereas the testing norms are well known for the general population, they are not well known for Veterans.

HOW MANY PEOPLE ARE BEING ASKED TO TAKE PART IN THE STUDY?

Our plan is to conduct the neurocognitive assessment with 300 post-9/11 Veterans who completed the CHAI Study survey.

DURATION OF THE RESEARCH

The neurocognitive assessment is expected to take approximately 1 hour.

STUDY PROCEDURES

If you decide to take part in this study, this is what will happen:

(1) We will spend the first few minutes asking you some preliminary questions about your health to see if there have been any significant changes since you completed your survey.

(2) During the remaining part of the hour, a trained interviewer will administer a series of tests that will ask you to do different types of tasks. For example, the interviewer may read a list of words aloud and ask you to repeat as many words as you remember. You may also be asked to complete some tasks on paper and other tasks on the computer. Before you start a test, the interviewer will provide you with instructions. In some of the tests, the interviewer will use a stopwatch to record the time it takes you to complete the task.

(3) Some tasks will seem easy to you, while others may seem more challenging. No one is able to perform perfectly or get everything correct on all of the tests. But, we do ask that you try your best on all of the tasks

(4) Feel free to ask the interviewer to repeat or explain the instructions so that you understand them.

(5) Participating in this test is voluntary and you may discontinue or reschedule the testing session for any reason. If at any point during the assessment you change your mind about completing the full hour long session, let us know and we will end the session

(6) Let us know if you need to take a break and we will pause the assessment until you are ready. Because some of the tasks are timed from start to finish, it may not always be possible to take a break in the middle of a task without invalidating the results. However, it is possible to take breaks in between tests.

(7) If you have had a previous neurocognitive assessment, you may recognize some of the tests. Please note that the hour long CHAI assessment is not a full clinical evaluation, and this is why it is not appropriate for us to provide you with the results of the testing.

POSSIBLE RISKS OR DISCOMFORTS

Some people are uncomfortable taking tests. Cognitive tests are designed to measure the limits of ability, and can be anxiety provoking as tasks become more difficult. Also, for many measures the test administrator is not allowed to provide feedback, which can also be anxiety provoking. Some people will find this testing to be fatiguing and may need a short break.

You are free to discontinue the testing at any time. Let us know if you need to take a break and we will pause the assessment until you are ready. If at any point during the assessment you change your mind about completing the full hour long session, let us know and we will end the session.

POTENTIAL BENEFITS

We can't promise you any direct benefits from taking part in this research study. However, the information you provide will help the VA understand the long-term consequences of military service for post-9/11 Veterans and translate this understanding into better meeting the current and future healthcare needs of post-9/11 Veterans and their families.

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CONFIDENTIALITY

Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:

Abt Associates

- The Consent and HIPAA Authorization forms with your name and signature will be kept in a locked filing cabinet in a locked office in the Abt Associates Silver Spring, MD secure, access-controlled office where only two staff will have access to the filing cabinet where the consent forms will be stored: the Project Director, Heather Hammer, Ph.D. and the Project Manager, Alisha Creel, Ph.D. When the study ends, Abt Associates will deliver a pdf copy of the forms to the VA prior to securely shredding the paper versions. The pdf copy will be kept by the VA Principal Investigator, Aaron Schneiderman, Ph.D., in accordance with VA Record Control Schedule 10-1 (RCS 10-1).
- Abt Associates computers are all password protected.
- Access to electronic data is restricted by username and password. Abt Associates also limits access to personally identifiable information (PII) based on a need-to-know policy.
- Everyone on the Abt Associates project team is required to sign a confidentiality agreement that specifies that no identification of respondents or their answers will be revealed to other persons that are not specifically involved with this project.
- Abt Associates has a Conditional Authorization to Operate (ATO) for the CHAI Study which allows the Abt Associates system to be compliant with VA policy temporarily until all information security requirements are met.
- All of Abt Associates procedures comply with the Privacy Act of 1974, Health Insurance Portability and Accountability Act of 1996 (HIPAA), and the E-Government Act of 2002, including Title III: Federal Information Security Management Act (FISMA), which covers site security, security control documentation, access control, change management, incident response, and risk management.
- Abt Associates creates a separate password protected and encrypted electronic "linking" file for each study. The linking file includes two variables: the participant name and a unique Abt

Associates ID Number. This file is separate from the interview data. Only the Project Director, Heather Hammer will have access to the linking file.

- The Neurocognitive Assessment data will include only your ID Number and not your name. At the end of the study Abt Associates will destroy all of the paper and electronic files that include your name or any other identifying information as specified in Abt Associates' contract with the VA.
- The information you provide will be combined with the information from the other people taking part in the study. We will write only about the combined data we have gathered. Any talks, reports or papers about this study will not identify you.
- Each member of the Abt Associates project team maintains current training certificates in the protection of sensitive data in addition to completing all of the study's security clearance requirements. All key personnel hold current Moderate Level Security Clearances with the VA.

The information collected for this study will be kept confidential. There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

Certificate of Confidentiality

To help protect the privacy of respondents we have obtained a **Certificate of Confidentiality** from the United States Department of Health and Human Services (DHHS). With this Certificate, the VA cannot be forced (for example by court order or subpoena) to disclose information that may identify you in any Federal, state, local, civil, criminal, legislative, administrative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except to prevent serious harm to you or others, and as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency 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, your family, or your involvement in this study. If an insurer or employer learns about your participation, and obtains your consent to receive research information, then we may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

DC WRIISC

The test results will be analyzed by professional neuropsychologists at the Washington DC War Related Illness and Injury Study Center (WRIISC). The WRIISC is a centrally funded multidisciplinary team tasked with the goal of providing second opinions, conducting research on war related injuries and disorders, and providing educational outreach. The CHAI Neurcognitive Assessments will be evaluated using the most current normative systems to provide the best comparison of function.

COSTS TO PARTICIPANTS AND PAYMENT

You will not be charged for any part of this study.

PAYMENT OFFERED FOR PARTICIPATION

- You will receive a check for $100 to compensate you for participating in this assessment. The Abt Associates technician will issue this check to you in person when you finish the interview.
- If you decide not to complete the assessment at any point after the session begins, you will still receive a check for $100. The Abt Associates technician will issue this check to you in person at the time that you withdraw.

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MEDICAL TREATMENT AND COMPENSATION FOR INJURY

Every reasonable safety measure will be used to protect your well-being. 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 was due to your not following the study procedures.

Note that the VA may not provide necessary medical care for treatment for injuries in research conducted for VA under contract with an individual or non-VA organization.

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

DURING THE DAY:
Dr./Mr./Ms. _____ at _____ and
AFTER HOURS:
Dr./Mr./Ms._____ at _____

Emergency and ongoing medical treatment will be provided as needed.

You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

PARTICIPATION IS VOLUNTARY

Your participation in this study is **voluntary**. You can refuse to take part in the study without penalty or loss of benefits to which you are otherwise entitled. 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 entitled. If you are a VA employee or student, refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress as applicable. You may discontinue taking part at any time without any penalty or loss of benefits.

If you decide to withdraw before you complete the cognitive interview, the investigator may continue to review the data collected for the study up until the time you withdraw, but cannot collect further information, except from public records.

PERSONS TO CONTACT ABOUT THIS STUDY

If you have any questions, complaints, and concerns about the research or related matters, you can contact Aaron Schneiderman, the Principal Investigator at 202-266-4695 or 1-800-211-5272.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

You understand the explanation of the Neurocognitive Assessment provided by this document. You have been informed of the risks or discomforts and possible benefits of the study. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. Please sign and date both copies of this Consent Form and the HIPAA Authorization Form, give one set to the interviewer and keep the other for your records. The copy of this signed forms that you give to the interviewer will be securely stored by Abt Associates until it is destroyed at the end of the study. When the study ends, Abt Associates will deliver a pdf copy of the forms to the VA prior to securely shredding the paper versions. The pdf copy will be kept by the VA Principal Investigator, Aaron Schneiderman, Ph.D., in accordance with VA Record Control Schedule 10-1 (RCS 10-1).

SUBJECT'S IDENTIFICATION VA Form **10-10-86** MAR 2006	**FOR VA CENTRAL IRB USE ONLY** **PI/SC Approval Date:** **LSI Approval Date:** **LSI Verification Date:**

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I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date
_____ Name of person obtaining consent	_____ Signature of person obtaining consent	_____ Date