



**Department of Veterans Affairs**

## **RESEARCH CONSENT FORM**

**CHAI Child Study Parent/Guardian Consent - Civilians**

**Version Date: May 21, 2017**

Participant Name: \_\_\_\_\_ Date: \_\_\_\_\_

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

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 permit your child 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 Comparative Health Assessment Interview (CHAI) Child Study is to compare the adolescent children of post-9/11 Veterans with the adolescent children of those who considered military service, but decided not to join the military after 9/11. The information collected by the study will help the VA understand, from the child's own perspective, if there are differences between having and not having a parent or guardian who served in the military and is now a Veteran.

### **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 Child Study is to help the VA understand how deployment and combat affect the families of Veterans from their children's point of view.

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

Our plan is to conduct the Child Study with 500 adolescent children of parents and guardians who completed the CHAI Study survey.

**DURATION OF THE RESEARCH**

The interview is expected to take approximately 45 minutes.

**STUDY PROCEDURES**

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

- (1) The Abt Associates interviewer will show you and your child his/her identification card and confidentiality pledge and spend the first few minutes with you and your child before asking you to leave the room so that your child's privacy is protected. Then the interviewer will review the Assent Form with your child to see if your child has any questions about the study and to ensure that your child is willing to participate.
- (2) During the 45 minute interview, the interviewer will administer the survey questionnaire to your child using a VA certified secure laptop and computer-assisted personal interviewing. The survey will start with some general demographic questions such as your child's age and grade, then move into more specific questions about attitudes and experiences related to the following topics:
  - Family, friends, neighborhood, school, interests, and future plans
  - Gender orientation
  - Physical and mental health
  - Substance use
  - Bullying and other peer violence
  - Dating
  - Religiosity
- (3) Your child is free to skip any question he/she prefers not to answer.

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- (4) Most of the questions ask your child to select the best answer from a list of response categories. However, there are also a few questions where your child will be asked to answer the questions in his/her own words. For example, "What is your favorite food?"
- (5) The time it takes to complete the questionnaire depends on each child's individual experience, but on average the survey takes 45 minutes.
- (6) We will ask your child to let us know if he/she needs to take a break and we will pause the interview until he/she is ready.
- (7) If at any point during the interview you or your child changes your mind about completing the survey, let us know and we will end the session.

**POSSIBLE RISKS OR DISCOMFORTS**

About half of the interview includes sensitive questions that ask your child for private information about his/her mental health and well-being, substance use, bullying and other peer violence, gender orientation, and dating and other relationships. Many of these questions are the same or similar to the types of age-appropriate questions asked in other youth surveys administered in middle and high school including the Youth Behavioral Risk Factor Survey and the Youth Tobacco Survey. However, even a seemingly neutral question can cause discomfort among some young people. For example, if your child has been held back in school, he/she might experience discomfort when asked what grade he/she is in school.

Your child is free to skip any questions that he/she prefers not to answer. We will instruct your child to let the interviewer know if he/she needs to take a break and we will pause the interview until he/she is ready. We will also tell you child that if at any point during the interview he/she child changes his/her mind about completing the survey session, he/she should let the interviewer know and we will end the session.

The potential risks or discomforts your child may experience as a result of participating in the Child Study are as follows:

- 1. Psychological distress.** The questionnaire includes items about mental health, substance use, and other life experiences that may cause your child discomfort or upset. Even a

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seemingly neutral question can have this affect among some young people. The questions that we ask are similar or identical to those that would be asked in other youth surveys administered in middle and high school including the Youth Behavioral Risk Factor Survey and the Youth Tobacco Survey, or in a routine physical or mental health screening. Abt Associates has extensive experience administering similar surveys to adolescents as young as 10 years of age, and in their experience, only a very small number of the children surveyed were uncomfortable or upset by the questions.

2. **Breach of confidentiality.** Any release, including inadvertent release of sensitive information that your child provides when he/she answers the survey questions could have serious social and psychological repercussions for your child. We have taken stringent precautions to protect the confidentiality of the information that we collect in this study and describe those precautions in the Confidentiality Section.
3. **Breach of privacy.** The potential for privacy breaches related to this study are as follows:
  - a. **Study-related Mail.** While all of the mail we sent you and your child related to this study was sealed and addressed to you or your child by name (including the fold over, sealed appointment reminder/confirmation postcard), there is always some risk that someone other than you or your child may have opened and/or read your or your child's mail.
  - b. The Child Study interview cannot be conducted without your written consent. Two signed consent forms are required, one for you to keep and one for us to keep for the duration of the study. The consent includes your name and Study ID Number and your child's name and Study ID Number, meaning that some unauthorized person may read the form and use it to identify you and your child as study participants.
  - c. Similarly, the Child Study interview cannot be conducted without your child's written assent. Two signed assent forms are required, one for your child to keep and one for us to keep for the duration of the study. The assent includes your child's name and Study ID Number and your name and Study ID Number, meaning that some unauthorized person may read the form and use it to identify you and your child as study participants.

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We have taken stringent precautions to protect the confidentiality of the information that we collect in this study and describe those precautions in the Confidentiality Section.

**POTENTIAL BENEFITS**

We can't promise you or your child any direct benefits from taking part in this research study. However, the information your child provides will be used to improve the VA's understanding of what it's like to have a parent or guardian who served in the military and is now a Veteran from the child's own perspective.

**CONFIDENTIALITY**

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

**Abt Associates**

- For the duration of the study, 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). The Assent Form with your child's name and signature will be protected using the same procedures.
- 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.

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- 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 Child Study data will include only your child's ID Number, your ID Number, and not your name or your child's name. At the end of the study, Abt Associates will destroy all of the paper and electronic files that include your name, your child's name, or any other identifying information as specified in Abt Associates' contract with the VA.
- The information your child provides 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 your child.
- 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. Your answers will not be shared with your parent/guardian. However, 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.

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**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.

**COSTS TO PARTICIPANTS AND PAYMENT**

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

**PAYMENT OFFERED FOR PARTICIPATION**

- Your child will receive a check for \$100 to compensate him/her for participating in the Child Study. The Abt Associates interviewer will issue the check to you or your child as requested, in person, when your child finishes the interview.
- If your child decides not to complete the interview at any point after the session begins, your child will still receive a check for \$100. The Abt Associates interviewer will issue the check to you or your child as requested, in person, at the time that your child withdraws.

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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 your child 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

Granting permission for your child to participate in this study is **voluntary**. You can refuse to allow your child 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 permit your child to take part in this study. If you decide to grant permission for your child to take part you may still withdraw your permission at any time. If you do not wish for your child to be in this study or your child leaves 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

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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 or your child decides to withdraw before your child completes the Child Study interview, the investigator may continue to review the data collected for the study up until the time you or your child withdraws, but cannot collect further information, except from public records.

**PERSONS TO CONTACT ABOUT THIS STUDY**

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

If you or your child have questions about your rights as a study participant, or to make sure this is a valid VA study, you or your child 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 or your child 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 Child Study 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.

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By signing this document below, you voluntarily consent to grant permission for your child 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.

For the duration of the study, the Consent Form and HIPAA Authorization Form 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).

**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

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