(Protocol Reference Number) Version #\_\_\_\_, Date: \_\_\_\_

## Naval Health Research Center, San Diego, CA CONSENT TO PARTICIPATE IN RESEARCH Parent Voluntary Consent Title: Health and Well-Being of Adolescents in Military Families

**Principal Investigator:** Valerie Stander, Ph.D.

You may be eligible to take part in this research study. This form gives you important information about the study.

Please take time to carefully review this information. You should talk to the researchers about the research study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or your personal physician) about your potential participation in this research study. You do not have to take part in this study. Participation is voluntary. You may also leave the research study at any time without penalization.

# 1. **KEY INFORMATION:**

## Participation is Voluntary

You are being asked to participate in a research study. Participation is completely voluntary. Please read the information below and ask questions about anything that you do not understand. The lead researcher listed above will be available to answer your questions.

# **Study Purpose**

The purpose of this research study is to discover how military experiences may impact militaryconnected adolescents and their families. From the information we learn in the study, we hope to provide information that will improve programs and services for military families.

# **Expected Duration of Participation**

Participation in the online survey will last approximately 30 minutes.

#### **Study Procedures**

As a participant in this study, you will be asked to complete a survey online with questions that ask about how you are feeling and your behaviors, behaviors your adolescent child may engage in, and your relationship with your adolescent child and their other parent (if applicable).

#### **Benefits to Participation**

You may not directly benefit from participation in this study. However, you will receive a summary of results from the study once it is completed. We will also provide a list of resources for families participating in the study.

#### Benefits to Others or Society

We believe that the information we can learn from this study will help researchers and decision makers understand how experiences of military-affiliated parents can affect their adolescent children's health and well-being. This information may be important in helping to identify and

Page **1** of **22** Effective Date: 2/27/2020 develop better interventions and programs for military families.

# **Risks of Participation**

We anticipate minimal risk for participating in this study. Possible risks of participation may include temporary discomfort or emotional distress caused by some of the questions on the survey or breach in data privacy.

# Alternative Procedures or Treatments

There are no alternative procedures available. The only alternative is not to participate in this study.

Your decision to participate in this study will not affect your future relationship with the Naval Health Research Center. If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.

Please tell the researchers if you are taking part in another research study.

NOTE: If you are providing consent as a legally authorized representative (LAR), "you" or "your" refers to the research participant.

# 2. <u>WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO</u> <u>WILL TAKE PART?</u>

You are being asked to take part in this research study because you or your spouse/partner are or have been in the military and are the parent or legal guardian of an adolescent child between the ages of 11 and 17 years old. The purpose of this research is to learn about how military experiences may impact your adolescent child's health and well-being. The duration of participation in the online survey is approximately 30 minutes.

There will be about 7,000 adolescent children and 9,450 parents taking part in this online study over a period of approximately two years.

# 3. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, you will need to provide some information so that the Investigator can confirm that you qualify for the study. This is called the "Screening Process." You must meet the following requirements to be in this study:

- Participated in the Millennium Cohort Study (or the spouse/partner of someone who has participated)
- Currently or previously in the military (or the spouse/partner of someone currently or previously in the military)
- Have at least one child between the ages of 11 and 17 years old who was alive during your or your spouse/partner's time in the military
- Have had contact with your 11-17 year old child in the last year
- Be fluent in English

• Have no significant cognitive impairments, developmental delays, or serious illnesses that would prevent you from accurately completing an online survey

# 4. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

- You will be asked to provide your voluntary consent prior to participating in this study. If you have an adolescent-age child who meets all of the eligibility criteria listed above, we will ask you to provide consent for your adolescent child to participate in the study as well. At that time, we will ask you to provide a way to contact the adolescent child directly to obtain their assent for participation. Your adolescent child should be in the company of a parent when assent is obtained. However, the survey should be completed online by the adolescent child in privacy to allow for them to be as honest as possible in their responses to questions. Parent consent and child assent forms must be completed online in order to participate in the study.
- As a participant in this study, you will be asked to complete a survey online and respond to some questions that ask about how you are feeling and your behaviors, behaviors your adolescent child may engage in, and your relationship with your adolescent child and their other parent (if applicable). Survey responses will be identified by subject number only (not your name) and will be deleted 5 years after the end of the study.
- Participation in the online survey will take approximately 30 minutes to complete.

# 5. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

If you choose to take part in this study, there is a risk that the questions may cause temporary discomfort or emotional distress. Research shows that individuals generally report lower distress as a result of being asked about their experiences. However, you do not have to answer any questions that make you feel uncomfortable.

Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you. However, every effort will be made to safeguard your information (see Q15 below).

# 6. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?

There are no direct benefits to you for taking part in the study. However, you and others may benefit in the future from the information learned during this study. The possible benefits to others are a better understanding of how experiences of military-affiliated parents can affect their adolescent children's health and well-being. This information may be important in helping to identify and develop better interventions and programs for military families.

# 7. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

There are no alternative procedures available. The only alternative is not to participate in this study.

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# 8. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

Yes, for your participation, you will receive a \$10 gift card of your choice to Amazon, Target, or Starbucks.

# 9. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

# 10. <u>PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study</u>):

Valerie Stander, Ph.D. valerie.a.stander.civ@mail.mil 619-553-7174

# 11. <u>STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):</u>

The institution overseeing this research is the Naval Health Research Center. As the funding sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02p.

#### 12. <u>SOURCE OF FUNDING:</u>

Office of the Deputy Assistant Secretary of Defense (DASD) for Military Community and Family Policy (MCFP)

# 13. LOCATION OF THE RESEARCH:

Naval Health Research Center, San Diego, CA

# 14. <u>DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL</u> <u>ARRANGEMENTS</u>:

There are no financial interests or other personal arrangements to disclose.

# 15. <u>WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE</u> <u>PROTECTED (CONFIDENTIALITY)?</u>

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Privacy Act of 1974, 5 U.S.C. 522a(b)(3), and its implementing regulations. A copy of the Privacy Act statement is provided to you for your records.

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The research team will keep your research records. These records may be looked at by staff from the Naval Health Research Center, the Institutional Review Board (IRB), and the DoD Higher Level Review as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

Procedures to protect the confidentiality of the data in this study include but are not limited to: Identifiable information collected about you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data. Personal identifiers (e.g., birth date) will be retained in order to establish an accurate timeline of when events occurred. Research data will be maintained in a secure location at the Naval Health Research Center. Only authorized individuals will have access to it. All electronic data will be stored in encrypted files on a secure server at the Naval Health Research Center. Any data shared with other researchers will not include your name or other personally identifying information. The researchers may continue to use and share your deidentified information indefinitely. Identifiable data will be destroyed 5 years after the end of the study.

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

For this research study, a Department of Health and Human Services (DHHS) Certificate of Confidentiality is in place to protect your privacy such as your name or other identifying information from being disclosed in any civil, criminal, administrative, legislative or other proceedings, whether at the federal, state or local level. The Certificate cannot be used to resist a demand for information from personnel of the U.S. 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 Food and Drug Administration (FDA). Further, the researcher is not prevented from disclosure for reporting matters such as family abuse, sexual assault, reportable communicable diseases, a participant's threatened violence to self or others, or as military regulations may require. You should understand that the 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.

The research team, authorized NHRC personnel, and regulatory entities such as the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare. While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy.

Those listed above will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

Information gained from your participation in this research study may be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified when your information is shared in these ways; all information will de-identified.

# **16. VOLUNTARY PARTICIPATION**

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled.

You will be informed if significant new findings develop during the course of this research study that may relate to your decision to continue participation.

# **17. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?**

Should you choose to withdraw, you must notify the research team immediately. If you elect to withdraw from this research study, the researchers will discuss with you what they intend to do with your study data. Researchers may choose to analyze the study data already collected or they may choose to exclude your data from the analysis of study data and destroy it, as per your request.

Please note that withdrawing your consent to participate in this research does not fully revoke your HIPAA Authorization Form to use/disclose your protected health information. To make that revocation, please send a letter to the principal investigator as discussed in the HIPAA Authorization Form.

The principal investigator of this research study may terminate your participation in this research study at any time if she determines this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

# 18. CONTACT INFORMATION:

# Principal Investigator (PI)

The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator: Valerie Stander, Ph.D. Phone: 619-553-7174 Mailing Address: Naval Health Research Center, San Diego, CA

# **Institutional Review Board (IRB) Office**

If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the IRB Chair, Lt Col Patricia Rohrbeck, at: Phone: 619-553-8424; Email: <u>usn.nhrc.irb@mail.mil</u>.

# IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated copy of this document will be given to you.

# SIGNATURE OF PARTICIPANT

By signing below, I agree that I have been provided time to read the information describing the research study in the consent form. The content and meaning of this information has been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study.

By signing this form, I have not given up any of my legal rights as a research participant.

Printed Name of Participant

Signature of Participant

Your signature below indicates you are legally authorized to act on behalf of the participant, and have read this document. You will receive a copy of this document.

# SIGNATURE OF LEGALLY AUTHORIZED REPRESENTATIVE

Printed Name of Legally Authorized Representative

Relationship to the Participant

Signature of Legally Authorized Representative

Date

Date

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## Naval Health Research Center, San Diego, CA CONSENT TO PARTICIPATE IN RESEARCH Parent Voluntary Consent for Minor Child Title: Health and Well-Being of Adolescents in Military Families Principal Investigator: Valerie Stander, Ph.D.

This study involves minor children/dependents, with an age range of 11–17 years. A separate assent of the child is required with the signature of the parent or guardian and the investigator. At times there may be inconsistency between the permission of the parent and the assent of the child. A rule of thumb is: a "no" from a child overrides a "yes" from the parent, but a "yes" from a child does not override a "no" from a parent. If the child reaches the age a majority (usually 18 years old) while enrolled in the study, the investigators will obtain the informed consent of the subject as an adult.

This form gives you important information about the study and must be completed online in order for your child to participate in the study. If you decide to provide consent for your child to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of this form.

## Participation is Voluntary

Your child is being asked to participate in a research study. Participation in this research study is completely voluntary. Your child may withdraw from the research study at any time without penalization. If your child elects to leave the study, the researchers will discuss with you what they intend to do with your child's data, which may include choosing to analyze the data already collected or excluding your child's data from the analysis. Please read the information below and ask questions about anything that you do not understand. If you have any questions, please contact the study PI, Dr. Valerie Stander, at <u>valerie.a.stander.civ@mail.mil</u> or 619-553-7174. You may also contact the NHRC Institutional Review Board at <u>USN.NHRC.IRB@mail.mil</u> or at 619-553-8424.

# **Study Purpose**

The purpose of this research study is to learn about how military experiences may impact your child's health and well-being. Your child is being asked to participate in this research study because of your service in the U.S. military. From the information we learn in the study, we hope to provide information that will improve programs and services for military families.

#### **Expected Length of Participation**

Participation in the online survey will last approximately 30 minutes.

#### **Study Procedures**

As a participant in this study, your child will be asked to complete a survey online and respond to some questions that ask about how your child is feeling, behaviors your child may engage in, and your child's relationship with you and their other parent, if applicable. Before your child starts the survey, they will be asked to provide their assent to participate. Your child should be in

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the company of a parent when assent is obtained. However, the survey should be completed online by your child in privacy to allow for your child to be as honest as possible in their responses to questions. Parent consent and child assent forms must be completed online in order to participate in the study. For your child's participation, they will receive a \$10 gift card of their choice to Amazon, Target, or Starbucks. There is no cost to your child for participation in this study.

## **Benefits to Participation**

Your child may not directly benefit from participation in this study. However, your child and others may benefit in the future from the information learned during this study. Possible benefits are a better understanding of how parents' military experiences can affect their adolescent child's health and well-being. This information will help to develop better interventions and programs for military families.

#### **Risks of Participation**

Possible risks of participation may include temporary discomfort or emotional distress caused by some of the questions on the survey. Your child does not have to answer any questions that make them feel uncomfortable. There is also a slight risk that someone outside of the research team could gain access to information stored about your child. Researchers will make every effort to protect your child's privacy and confidentiality. Survey responses will be identified by subject number only (not your child's name) and your child's identifiable information will be kept separate from the research data. Data will be maintained in a secure location at NHRC and only authorized individuals will have access to it. All electronic data will be stored in encrypted files on a secure server at NHRC. Any data shared with other researchers will not include your child's name or other personal identifying information. Identifiable data will be destroyed 5 years after the end of the study.

#### Alternative Procedures or Treatments

There are no alternative procedures available. The only alternative is not to participate in this study.

Your decision to provide consent for your child to participate in this study will not affect your or your child's future relationship with the Naval Health Research Center. You should not sign this consent form until all of your questions about this study have been answered by the researcher listed at the top of this form. You will be able to print a copy of this consent form to keep. By signing this consent form, you freely give your consent for your child to be in this research study as it has been explained to you.

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# SIGNATURE OF PARENT OR GUARDIAN

Printed Name of Parent or Guardian

Signature of Parent or Guardian

Date

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#### Naval Health Research Center, San Diego, CA **ASSENT TO PARTICIPATE IN RESEARCH Adolescent Voluntary Assent Title:** Health and Well-Being of Adolescents in Military Families **Principal Investigator:** Valerie Stander, Ph.D.

This form gives you important information about the study and must be completed online in order to participate in the study. If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of this form. You should be in the company of a parent when your assent is obtained. However, the survey should be completed online in privacy to allow you to be as honest as possible in your responses to questions.

#### **Participation is Voluntary**

Participation in this research study is completely voluntary. You may leave the research study at any time without penalization. If you have any questions, please contact the study PI, Dr. Valerie Stander, at <u>valerie.a.stander.civ@mail.mil</u> or 619-553-7174.

## **Study Purpose**

You are being asked to participate in this research study because you are an 11–17 year old child of a parent who is serving or has served in the U.S. military. The purpose of this research is to learn about how military experiences may impact your health and well-being.

# **Expected Length of Participation**

Participation in the online survey will last approximately 30 minutes.

#### **Study Procedures**

As a participant in this study, you will be asked to complete a survey online and respond to some questions that ask about how you are feeling, your behaviors, and your relationship with your parent(s). For your participation, you will receive a \$10 gift card of your choice to Amazon, Target, or Starbucks.

#### **Benefits to Participation**

You may not directly benefit from participation in this study. However, you and others may benefit in the future from the information learned during this study. Possible benefits are a better understanding of how parents' military experiences can affect their adolescent child's health and well-being. This information will help to develop better interventions and programs for military families.

#### **Risks of Participation**

Possible risks of participation may include temporary discomfort or emotional distress caused by some of the questions on the survey. You do not have to answer any questions that make you feel uncomfortable. There is also a slight risk that someone could get access to information researchers have stored about you. Researchers will make every effort to protect your privacy

Page **11** of **22** Effective Date: 2/27/2020 and confidentiality. Survey responses will be identified by subject number only (not your name) and will be deleted 5 years after the end of the study.

#### Alternative Procedures or Treatments

There are no alternative procedures available. The only alternative is not to participate in this study.

## SIGNATURE OF PARTICIPANT

By signing below, I agree that I have been provided time to read the information describing the research study in the assent form. The content and meaning of this information has been explained to me. I have been provided with the opportunity to ask questions. I voluntarily assent to participate in this study.

Printed Name of Participant

Signature of Participant

Date

# PRIVACY ACT STATEMENT

#### You have rights under the Privacy Act. The following statement describes how that Act applies to this study:

The Privacy Act System of Records Notice (SORN) for this study is N6500-1. The SORN was published in the Federal Register on November 14, 2014 and is also published on the Defense Privacy and Civil Liberties Division (DPCLD) website and can be found by visiting: http://dpcld.defense.gov/Privacy/SORNsIndex/DODComponentArticleView/tabid/7489/ Article/570396/n06500-1.aspx

**Authority:** Authority to request this information is granted under: 10 USC 136, Under Secretary of Defense for Personnel and Readiness, 10 USC 1782, Surveys of Military Families, 10 USC 2358, Research and Development Projects, Under Secretary of Defense Memorandum #: 99-028, 30 SEP 99 "Establishment of DoD Centers for Deployment Health" and Executive Order 9396, Numbering System for Federal Accounts Relating to Individual Persons.

Purpose: To create a probability-based database of service members and veterans who have 11-17 year old adolescent children. The database will be used: (a.) To systematically collect population-based demographic and health data to evaluate the health of Armed Forces personnel and their adolescent children throughout their careers and after leaving the service. (b.) To evaluate the impact of operational deployments on various measures of health over time including medically unexplained symptoms and chronic diseases for parents and their adolescent children. (c.) To serve as a foundation upon which other routinely captured medical and deployment data may be added to answer future questions regarding the health risks of operational deployment, occupations, and general service in the Armed Forces for parents and their adolescent children. (d.) To examine characteristics of service in the Armed Forces associated with common clinician-diagnosed diseases and with scores on several standardized self-reported health inventories for physical and psychological functional status for parents and their adolescent children. (e.) To provide a data repository and available representative Armed Forces cohort that future investigators and policy makers might use to study important aspects of service in the Armed Forces including health and well-being outcomes among an Armed Forces cohort and their adolescent children.

In addition to revealing changes in Service member, veteran, partner, and children's health status over time, the Millennium Cohort Adolescent Study will serve as a data repository, providing a solid foundation upon which additional epidemiological studies may be constructed.

**Routine Uses:** The information provided in this questionnaire will be maintained in data files at the Deployment Health Research Department at the Naval Health Research Center and used only for research purposes. Use of these data may be granted to other federal and non-federal medical research agencies as approved by the Naval Health Research Center's Institutional Review Board. In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 522a(b)(3).

To the Department of Veterans Affairs (DVA) for (1) considering individual claims for benefits for which that DVA is responsible; and (2) for use in scientific, medical and other analysis regarding health outcomes research associated with military service. To the Department of Health and Human Services, Centers for Disease Control and Prevention for use in scientific, medical and other analysis regarding health outcome research associated with military service.

NOTE: All disclosures to the DVA and HHS must have prior approval of the Naval Health Research Center Institutional Review Board and a Memorandum of Understanding must be entered into to ensure the right and obligations of the signatories are clear. Access to data 1) is provided on need-to-know basis only; 2) must adhere to the rule of minimization in that only information necessary to accomplish the purpose for which the disclosure is being made is releasable; and 3) must follow strict guidelines established in the data sharing agreement. To the Social Security Administration (SSA) for considering individual claims for benefits for which that SSA is responsible. The DoD 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems of records notices apply to this system.

NOTE: This system of records contains individually identifiable health information. The DoD Health Information Privacy Regulation (DoD 6025.18-R) issued pursuant to the Health Insurance Portability and Accountability Act of 1996, applies to most such health information. DoD 6025.18-R may place additional procedural requirements on the uses and disclosures of such information beyond those found in the Privacy Act of 1974 or mentioned in this system of records notice.

**Voluntary Disclosure:** Completion of the questionnaire is voluntary. Failure to respond to any of the questions will NOT result in any disadvantages or penalties except possible lack of representation of your views in the final results and outcomes.

# **Agency Disclosure Notice**

The public reporting burden for this collection of information, OMB Control Number XXXX-XXXX, is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or burden reduction suggestions to the Department of Defense, Washington Headquarters Services, at whs.mc-alex.esd.mbx.dd-dodinformation-collections@mail.mil. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number.

# AUTHORIZATION TO USE OR DISCLOSE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

## Principal Investigator (PI) Name and Rank: Valerie A. Stander, Ph.D.

Corps and Service/Organization: Naval Health Research Center (NHRC)

## Title of Research Study: Military Connected Adolescents' Health and Well-Being

## I. Purpose of this Document

An Authorization is your signed permission to use or disclose <u>your</u> health information. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, as implemented by the Department of Defense (DoD), permits the Military Health System (MHS) to use or disclose your health information with a valid Authorization. The MHS is defined as all DoD health plans and DoD health care providers that are organized under the management authority of, or in the case of covered individual providers, assigned to or employed by, the Defense Health Agency (DHA), the Army, the Navy, or the Air Force. A valid Authorization must include the core elements and required statements as contained in this document.

The purpose of this form is to give your permission to the research team at the Naval Health Research Center (NHRC) to obtain, use or share your protected health information (PHI). This protected health information will be used to do the research named above. NHRC understands that information about you and your health is personal and we are committed to protecting the privacy of that information in accordance with state and federal privacy laws. Because of this commitment, we must obtain your written authorization before we may collect, use or share your protected health information for the research study listed above. This form provides authorization and helps us make sure you are properly informed of how this information will be used or disclosed. You do not have to sign this permission form. If you do not sign, NHRC will not obtain, use or share your protected health information for research. Your decision to not sign this permission will not affect any treatment, health care, enrollment in health plans or eligibility for benefits.

Please read the information below and ask questions about anything you do not understand before deciding to give permission for the use and disclosure of your health information.

#### **II.** Authorization

The following describes the purposes of this research study:

The Office of the Deputy Assistant Secretary of Defense (DASD) for Military Community and Family Policy (MC&FP) is sponsoring this research to understand the needs of military-connected youth and their families. The overarching aim of this study is to assess how military experiences are related to adolescents' psychosocial adjustment and physical health, academic achievement, and educational/military career aspirations and to identify risk and protective factors that may increase or decrease positive outcomes among military-connected adolescents and their families.

If you participate in this study, you will be asked to complete an online survey, which will take you about 30 minutes of your personal time to complete. Information about your health will be extracted from medical records and combined with the information you provide in the survey. Used together, this information will provide a more complete picture of your and your adolescent child's needs.

#### A. What health information will be used or disclosed about you?

If you sign this form, you give NHRC permission to obtain, use, or share the following health information as part of this research study: Medical history including results of physical examinations, lab tests, or certain health information indicating or relating to a particular condition; treatment and health services; hospital

discharge summary; emergency department records; psychological testing; progress notes; and financial billing records.

NHRC is required by law to protect your health information. By signing this form, you authorize NHRC to obtain, use, or share your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them.

# B. Who will be authorized to use or disclose (release) your health information to the researcher for this study?

The health information described above may be generated or obtained from:

- 1. Research survey data collected from you during the course of this research study.
- 2. Healthcare provider(s) who provided services to you or analyze your health information for clinic use within the TRICARE Prime, Standard, Select, or TRICARE remote networks.

Your protected health information may be obtained, used, or shared with these individuals or organizations for the following purposes:

- 3. To the research team for the research described in the Research Consent Form;
- 4. To others with authority to oversee the research (i.e., Institutional Review Board [IRB], safety monitoring committee, oversight board, etc.).

Any protected health information disclosed pursuant to the authorization may be subject to re-disclosure by the recipient and is no longer protected.

#### C. Who may receive your health information?

If you agree to be in this study, the research team may use or share your protected health information in the following ways:

- NHRC will receive and process your protected health information. Once all research records collected about you in support of this study have been obtained and merged with your health information, all subject identifiers will be removed from final analytic datasets.
- Any collaborator outside of the NHRC research team will receive access to final deidentified datasets. No individually identifying information will be shared with collaborators outside of the NHRC research team.
- IRBs or Data Safety and Monitoring Boards may have access to your records to ensure compliance with all DoD regulations and with required protocols for the protection of research participants.

#### D. What if you decide not to sign this Authorization?

You do not have to sign this Authorization. If you do not sign, NHRC will not obtain, use, or share your protected health information for research. Your decision not to sign this Authorization will not affect any treatment, health care, enrollment in health plans or eligibility for benefits, even those that may be associated with this study. The MHS **will not** condition (withhold or refuse) treatment that is not part of this study, payment, enrollment, or eligibility for benefits on whether you sign this Authorization.

#### E. Is your health information requested for <u>future</u> research studies?

No, your health information *is not* requested for future research studies.

# AUTHORIZATION TO USE OR DISCLOSE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

#### F. Can you access your health information during the study?

You may have access to your health information at any time, unless your identifiers are permanently removed from the data. Identifiers will be retained during and for a period of 5 years after completion of this study. To obtain a copy of your personal research records, you may submit a written request to the study Principal Investigator:

Valerie A. Stander, Ph.D. Naval Health Research Center 140 Sylvester Road San Diego, CA 92106

#### G. Can you revoke this Authorization?

- You may change your mind and revoke (take back) your Authorization at any time. However, if you revoke this Authorization, any person listed above may still use or disclose any already obtained health information as necessary to maintain the integrity or reliability of this research.
- If you revoke this Authorization, you may no longer be allowed to participate in this research study.
- If you want to revoke your Authorization, you must write to:

Valerie A. Stander, Ph.D. Naval Health Research Center 140 Sylvester Road San Diego, CA 92106

#### H. Does this Authorization expire?

Yes, it expires at the end of the research study.

#### I. What else may you want to consider?

- No publication or public presentation about the research described above will reveal your identity without another signed Authorization from you.
- If all information that does or can identify you is removed from your health information, the remaining deidentified information will no longer be subject to this Authorization and may be used or disclosed for other purposes.
- In the event your health information is disclosed to an organization that is not covered by HIPAA, the privacy of your health information cannot be guaranteed.

# AUTHORIZATION TO USE OR DISCLOSE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

#### Signature of Research Participant or Personal Representative:

Your signature acknowledges that:

- You authorize the MHS to use and disclose your health information for the research purposes stated above.
- You have read (or someone has read to you) the information in this Authorization.
- You have been given a chance to ask questions, and all of your questions have been answered to your satisfaction.

Participant Signature

Date

Participant Printed Name

# AUTHORIZATION TO USE OR DISCLOSE HEALTH INFORMATION THAT IDENTIFIES YOUR MINOR CHILD FOR A RESEARCH STUDY

Principal Investigator (PI) Name and Rank: Valerie A. Stander, Ph.D.

Corps and Service/Organization: Naval Health Research Center (NHRC)

# Title of Research Study: Military Connected Adolescents' Health and Well-Being

# I. Purpose of this Document

An Authorization is your signed permission to use or disclose <u>your child's</u> health information. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, as implemented by the Department of Defense (DoD), permits the Military Health System (MHS) to use or disclose your child's health information with a valid Authorization. The MHS is defined as all DoD health plans and DoD health care providers that are organized under the management authority of, or in the case of covered individual providers, assigned to or employed by, the Defense Health Agency (DHA), the Army, the Navy, or the Air Force. A valid Authorization must include the core elements and required statements as contained in this document.

The purpose of this form is to give your permission to the research team at the Naval Health Research Center (NHRC) to obtain, use or share your child's protected health information (PHI). This protected health information will be used to do the research named above. NHRC understands that information about your child's health is personal and we are committed to protecting the privacy of that information in accordance with state and federal privacy laws. Because of this commitment, we must obtain your written authorization before we may collect, use or share your child's protected health information for the research study listed above. This form provides authorization and helps us make sure you are properly informed of how this information will be used or disclosed about your child. You do not have to sign this permission form. If you do not sign, NHRC will not obtain, use or share your child's protected health information for research. Your decision to not sign this permission will not affect any treatment, health care, enrollment in health plans or eligibility for benefits for your child.

Please read the information below and ask questions about anything you do not understand before deciding to give permission for the use and disclosure of your child's health information.

# **II.** Authorization

The following describes the purposes of this research study:

The Office of the Deputy Assistant Secretary of Defense (DASD) for Military Community and Family Policy (MC&FP) is sponsoring this research to understand the needs of military-connected youth and their families. The overarching aim of this study is to assess how military experiences are related to adolescents' psychosocial adjustment and physical health, academic achievement, and educational/military career aspirations and to identify risk and protective factors that may increase or decrease positive outcomes among military-connected adolescents and their families.

If your child participates in this study, your child will be asked to complete an online survey, which will take your child about 30 minutes of their personal time to complete. Information about your child's health will be extracted from medical records and combined with the information you and your child provide in the survey. Used together, this information will provide a more complete picture of your adolescent child's needs.

#### A. What health information will be used or disclosed about your child?

If you sign this form, you give NHRC permission to obtain, use, or share the following health information as part of this research study: Medical history including results of physical examinations, lab tests, or certain

health information indicating or relating to a particular condition; treatment and health services; hospital discharge summary; emergency department records; psychological testing; progress notes; and financial billing records.

NHRC is required by law to protect your child's health information. By signing this form, you authorize NHRC to obtain, use, or share your child's health information for this research. Those persons who receive your child's health information may not be required by Federal privacy laws to protect it and may share your child's information with others without your permission, if permitted by laws governing them.

# B. Who will be authorized to use or disclose (release) your child's health information to the researcher for this study?

The health information described above may be generated or obtained from:

- 1. Research survey data collected from you or your child during the course of this research study.
- 2. Healthcare provider(s) who provided services to your child or analyze your child's health information for clinic use within the TRICARE Prime, Standard, Select, or TRICARE remote networks.

Your child's protected health information may be obtained, used, or shared with these individuals or organizations for the following purposes:

- 3. To the research team for the research described in the Research Consent Form;
- 4. To others with authority to oversee the research (i.e., Institutional Review Board [IRB], safety monitoring committee, oversight board, etc.).

Any protected health information disclosed pursuant to the authorization may be subject to re-disclosure by the recipient and is no longer protected.

#### C. Who may receive your child's health information?

If you agree for your child to be in this study, the research team may use or share your child's protected health information in the following ways:

- NHRC will receive and process your child's protected health information. Once all research records collected about your child in support of this study have been obtained and merged with your child's health information, all subject identifiers will be removed from final analytic datasets.
- Any collaborator outside of the NHRC research team will receive access to final deidentified datasets. No individually identifying information will be shared with collaborators outside of the NHRC research team.
- IRBs or Data Safety and Monitoring Boards may have access to your child's records to ensure compliance with all DoD regulations and with required protocols for the protection of research participants.

#### D. What if you decide not to sign this Authorization?

You do not have to sign this Authorization. If you do not sign, NHRC will not obtain, use, or share your child's protected health information for research. Your decision not to sign this Authorization will not affect any treatment, health care, enrollment in health plans or eligibility for benefits, even those that may be associated with this study. The MHS **will not** condition (withhold or refuse) treatment that is not part of this study, payment, enrollment, or eligibility for benefits on whether you sign this Authorization.

#### E. Is your child's health information requested for future research studies?

# AUTHORIZATION TO USE OR DISCLOSE HEALTH INFORMATION THAT IDENTIFIES YOUR MINOR CHILD FOR A RESEARCH STUDY

No, your child's health information *is not* requested for future research studies.

#### F. Can you access your child's health information during the study?

You may have access to your child's health information at any time, unless your child's identifiers are permanently removed from the data. Identifiers will be retained during and for a period of 5 years after completion of this study. To obtain a copy of your child's personal research records, you may submit a written request to the study Principal Investigator:

Valerie A. Stander, Ph.D. Naval Health Research Center 140 Sylvester Road San Diego, CA 92106

#### G. Can you revoke this Authorization?

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- If you revoke this Authorization, you may no longer be allowed to participate in this research study.
- If you want to revoke your Authorization, you must write to:

Valerie A. Stander, Ph.D. Naval Health Research Center 140 Sylvester Road San Diego, CA 92106

#### H. Does this Authorization expire?

Yes, it expires at the end of the research study.

#### I. What else may you want to consider?

- No publication or public presentation about the research described above will reveal your child's identity without another signed Authorization from you.
- If all information that does or can identify your child is removed from your child's health information, the remaining de-identified information will no longer be subject to this Authorization and may be used or disclosed for other purposes.
- In the event your child's health information is disclosed to an organization that is not covered by HIPAA, the privacy of your child's health information cannot be guaranteed.

# AUTHORIZATION TO USE OR DISCLOSE HEALTH INFORMATION THAT IDENTIFIES YOUR MINOR CHILD FOR A RESEARCH STUDY

#### Signature of Parent/Guardian or Personal Representative:

Your signature acknowledges that:

- You authorize the MHS to use and disclose your child's health information for the research purposes stated above.
- You have read (or someone has read to you) the information in this Authorization.
- You have been given a chance to ask questions, and all of your questions have been answered to your satisfaction.

Parent/Guardian Signature

Date

Parent/Guardian Printed Name

Minor Child's Printed Name