

Naval Health Research Center, San Diego, CA
CONSENT TO PARTICIPATE IN RESEARCH Voluntary Consent
Title: Millennium Cohort Study of Adolescent Resilience (SOAR)
Principal Investigator: Hope McMaster, Ph.D.

This form gives you important information about the study. Your parent previously provided voluntary consent for you to participate in this survey. Because you are 18 years or older, you must now provide consent for yourself. We hope you continue to participate in this 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 the Millennium Cohort Study of Adolescent Resilience (SOAR). Participation is completely voluntary. Please read the information below and ask questions about anything that you do not understand. The Principal Investigator of this study, Dr. Hope McMaster, will be available to answer your questions via email at hope.m.mcmaster.civ@health.mil or via telephone at 619-767-4624.

Study Purpose

The purpose of this research study is to discover how military experiences may impact military-connected 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, and your relationship with your adolescent parents and peers.

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.

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 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 confidentiality.

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 check a box at the end of this document. Before you check the box at the end of 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.

2. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

You are being asked to take part in this research study because your parent or legal guardian is or has been in the military and is enrolled in the Millennium Cohort Study of Service Members and Veterans. The purpose of this research is to learn about how military experiences may impact adolescent health and well-being. The duration of participation in the online survey is approximately 30 minutes.

There will be about 4,000 adolescents taking part in this online study conducted by the Naval Health Research Center.

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

Your parent previously provided consent for you to participate in this research study. Because you are 18 years or older, you now have to provide consent to participate yourself.

4. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS

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 Section 15 below).

5. 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.

6. 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.

7. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

Yes, for your participation, you will receive a \$20 electronic gift card to Amazon.com. Adolescents 18 years or older who are Service Members must agree to be off-duty when participating in this research.

8. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

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

9. PRINCIPAL INVESTIGATOR the person(s) responsible for the scientific and technical direction of the study):

Hope McMaster, Ph.D.
hope.m.mcmaster.civ@health.mil
619-767-4624

10. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):

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.

11. SOURCE OF FUNDING:

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

12. LOCATION OF THE RESEARCH:

Naval Health Research Center, San Diego, CA

13. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

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

14. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

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 (and any other Federal laws), 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at:

<https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2005.pdf>



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.

15. 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. If you choose to participate in this study, you may be invited to participate in follow-up surveys or substudies in the future. Your choice to participate in this study is completely independent of your choice to accept or reject any future research invitations. You may also leave this research study at any time. If you choose not to take part in this research study or if you leave this 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.

16. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

Should you choose to withdraw from this research study, 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: Hope McMaster, Ph.D.

Phone: 619-767-4624

Email: hope.m.mcmaster.civ@health.mil

Mailing Address: Naval Health Research Center, 140 Sylvester Road, San Diego, CA
92106-3521

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 at: Phone: 619-618-6102
Email: usn.nhrc.irb@health.mil.

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

A copy of this document will be given to you.

CONSENT OF PARTICIPANT

By checking the box 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 checking the box below, I have not given up any of my legal rights as a research participant.

- Yes, I agree.
- No, I do not agree.

