Meets 2018 Common Rule Requirements

Naval Health Research Center
CONSENT TO PARTICIPATE IN RESEARCH
Title: Upstream risk factors for behavioral health and suicide in military personnel: An examination of social determinants of health
Principal Investigator: Kristen H. Walter, 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:** The following focused information is being presented to assist you in understanding the key elements of this study, as well as the basic reasons why you may or may not wish to consider taking part. This section is only a summary; more detailed information, including how to contact the research team for additional information or questions, follows within the remainder of this document.

    a. We invite you to consent to take part in a research study examining investigating the health and social needs of active duty Sailors and Marines. The purpose of this study is to develop a survey that can identify risk factors for the future development of behavioral health symptoms. Signing a consent form and participating in this research is voluntary.

    b. You are being asked if you would like to participate in this study because you are an active duty Sailor or Marine. This study is being conducted by researchers at the Naval Health Research Center (NHRC) and the San Diego State University (SDSU), with funding from the Military Operational Medicine Research Program (MOMRP/JPC-5).

    c. Your participation in this research will involve taking part in two 15-minute online surveys. Total participation is expected to take approximately 30-45 minutes over 6 months.

    d. This survey can be completed at a time convenient for you and on a personal electronic device. If you complete this survey in off-duty hours, you will be eligible for compensation for your participation. The survey is entirely confidential. Your responses to survey items will not be linked to any information that could identify you. Your responses will also not be shared with your command.

e. If you take part in this study, there is a small potential risk of loss of privacy and/or confidential information about you. This is explained in more detail in the full consent form.

f. If you take part in this study, it is possible that you may feel some discomfort about answering questions during the online survey. At any time, if you feel uncomfortable, you may skip any specific survey questions or discontinue your participation with no consequences.

Your decision will not affect your future care at 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.

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 you are an active-duty Sailor or Marine. The purpose of this research study is to learn about the health and social needs of active duty Sailors and Marines in order to develop a survey that will identify risk factors for the development of behavioral health symptoms. The total duration of participation in this survey is 30-45 minutes over 6 months.

There will be about 1088 Sailors and Marines taking part in this study over a period of approximately one year. At the end of this research study, the results, including research results about you will not be shared with you.

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". This study's screening process will ask you to confirm information regarding your age, active duty status, future separation or deployment plans, contact information, and willingness to receive study information via email.

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

You will: participate in two 15-minute online surveys. This survey can be completed at a time convenient for you and on a personal electronic device. During this survey you will be asked about medical, social, and mental health, including questions related to housing, social support, discrimination, financial stability, and behavioral health symptoms. The survey is entirely confidential. Your responses to survey items will not be linked to any information that could identify you. If you complete this survey during off-duty hours, you will be eligible for compensation for your participation.

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 of:

Discomfort of answering sensitive questions: Some of the questions we ask could make you feel uncomfortable. You can choose not to answer any question without any negative consequences.

Loss of anonymity or confidentiality: Confidentiality will be maintained to the degree permitted by the technology used. Although data are encrypted using a secure server, your participation in this online screening survey involves risks like a person's everyday use of the Internet. For example, if you complete this survey in a public location, it is possible that others may see your responses. In addition, there is always the possibility of tampering from an outside source when using the internet for collecting information. While the confidentiality of your responses will be protected once the data are downloaded from the internet, there is always a possibility of hacking or other security breaches that could threaten the confidentiality of your responses. Please know that you are free to decide not to answer any question.

All your survey data will be anonymous, as we will not record your name or other identifying information or your IP address on the survey. However, after completing the survey, you will be redirected to a new and separate survey (that can only be accessed from the end of the survey) where you will enter your email address so that we can deliver your study incentive. Only one incentive per survey, per participant will be delivered.

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.

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

There are no direct benefits to you for taking part in the study. However, others may benefit in the future from the information learned during this study. Possible benefits to others in the future include a better understanding of the risk factors for the development of behavioral health symptoms among Sailors and Marines.

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

Your alternative is not to participate in this research.

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

Yes, for your participation, you will receive: a $15 gift code to Amazon once you have completed the first survey and a $25 gift code to Amazon.com after you complete the second survey, as long as surveys are taken while you are off duty. You can receive up to $40 for participation in this study.

9. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

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

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

Dr. Kristen Walter, NHRC Site Principal Investigator:
(619) 540-4108; kristen.h.walter.civ@mail.mil

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

This study is being conducted by Dr. Kristen Walter, PI, at the Naval Health Research Center and Dr. Emily Schmied at San Diego State University.

As the sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02p.

12. SOURCE OF FUNDING:

This study is being conducted with funding from the Military Operational Medicine Research Program's (MOMRP/JPC-5) Early Assessment & Interventions Working Group.

13. LOCATION OF THE RESEARCH:

This study is being conducted by researchers at the Naval Health Research Center (NHRC) and the San Diego State University (SDSU) in San Diego, California.

14. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

There are no financial interests or other personal arrangements to be disclosed.

15. 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 Federal Privacy Act, 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, Naval Medical Center San Diego, San Diego State University, as well as 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:

a. Information about you will be handled as confidentially as possible. There will be no paper research records. All interview and questionnaire data will be collected and stored electronically. We will not link your data with any personally identifying information (e.g., name, email address). We will not share your name with others and we will follow legal requirements carefully as we maintain your records. Federal regulations give certain rights related to health information. This includes the right to know who will have access to this information.

b. Only study members will have access to your data. Electronic data will be stored on secure password-protected servers. These records may be viewed by representatives of the DoD (e.g., Human Research Protection Program staff, the NHRC Institutional Review Board, the Department of the Navy Human Research Protection Program (DoN HRPP) as part of their normal 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. Your name will not appear in any published paper or presentation related to this study.

c. Access to all data will be limited to the staff involved in this study, and results may be published in DoD technical reports, scientific journals, or presented at scientific meetings. No publication or presentation about the research study described above will reveal your identity. Lastly, individuals from official government agencies, such as the Department of Defense and the U.S. Navy may inspect your research records to ensure that the rights and safety of all research participants are protected.

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

Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

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. LONG TERM USE OF DATA

The investigator has requested to save selected data collected from your participation in this research study for possible use in future research. All data you provide will be de-identified, meaning that the information will not be associated with your name, or any other method of identifying you. This data will remain stored on secure password-protected servers at NHRC and SDSU; data will only be shared with IRB approved researchers. Dr. Walter and Dr. Schmied (NHRC and SDSU investigators) will maintain responsibility for the data. You may also choose either to not allow any further use of your data to be used in future studies. This future research may be in the same area as the original study or it may be for a different kind of study. You will be provided choices at the end of this consent form to allow or deny use in future research studies.

Any future research using your retained data will require a research protocol for the proposed study approved by an Institutional Review Board (IRB) (a committee responsible for protecting research participants) or other authorized official responsible for protecting human subjects of research. The data protections for privacy and confidentiality described in this consent form will apply to any future use of your stored data.

17. USE OF INFORMATION AND SPECIMENS

The information and/or specimens that we obtain from you for this study might be used for future studies. All data used for future research will be de-identified.

18. INCIDENTAL FINDINGS

No incidental findings are expected to result from this research.

19. 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.

20. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

Should you choose to withdraw, you must write to the person in charge of the study, Dr. Kristen Walter at kristen.h.walter.civ@health.mil. When you revoke permission, no new information will be gathered after that date. You will no longer be allowed to continue your participation in the study, and you will not receive the $15 or $25 Amazon gift codes. Information that has already been gathered will still be

used. If you do not follow these procedures, you may still be considered a participant, and your data may continue to be collected and stored.

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.

21. 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: Kristen H. Walter, PhD
Phone: (619) 540-4108
Mailing Address: kristen.h.walter.civ@health.mil

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 Office at:
Phone: (619) 553-8424.; Email: usn.nhrc.irb@health.mil.

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 Date

PERMISSION FOR LONG-TERM USE OF DATA

- I give permission for my data to be used in future studies.
- I do not give permission for my data to be used in future studies.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date