Meets 2018 Common Rule Requirements

Naval Health Research Center
CONSENT TO PARTICIPATE IN RESEARCH
Title: *Male-identified survivors Of Sexual Assault – Investigating Challenges around seeking help (MOSAIC)*
Principal Investigator: *Kristen Walter, PhD*

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.

OMB CONTROL NUMBER: 0703-MSIC
OMB EXPIRATION DATE: XX/XX/XXXX

AGENCY DISCLOSURE NOTICE

The public reporting burden for this collection of information, 0703-MSIC, is estimated to average 60 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-dod-information-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.

1. KEY INFORMATION:

You are being asked to volunteer to participate in a research study titled, "Male-identified survivors Of Sexual Assault – Investigating Challenges around seeking help (MOSAIC)." Your participation is completely voluntary. We are inviting you to take part in a remote one-on-one phone interview.

You can choose not to participate or you can change your mind to participate at any time. There will be no negative consequences or repercussions if you choose not to participate.

This research is being conducted by researchers at the Naval Health Research Center (NHRC) in San Diego, California with funding from the Department of the Navy Office of Force Resiliency.

Purpose
The purpose of the study is to gain a greater understanding of the barriers and facilitators of help-seeking behaviors among male survivors of military sexual trauma.

Duration
Your participation in the research involves spending approximately 60 minutes during your off-duty or liberty time on one occasion.

Activities
We will be asking you to take part in a remote one-on-one phone interview about your experiences with seeking help following unwanted sexual contact or harassment during your time serving in the military.

Benefits
You may not directly benefit from participation in this study. However, the information from this research study may help researchers improve sexual assault reporting policies and practices in the military, as well as increase access to support resources and services for survivors of sexual assault and harassment.

Risks
The primary risk to you in taking part in this study may include temporary discomfort or emotional distress caused by some of the questions during the interview. There is also a potential risk of loss of privacy and/or confidential information about you.

Compensation
You will receive a gift card valued at $40 for your participation in the study. If you are an active duty Sailor you must participate in this study during your off-duty time to receive the gift card.

If you decide to take part in this research study, you will be asked to provide consent by checking a box at the bottom of this document. Before you provide consent, 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 identify as male and you are an active duty Sailor or Navy veteran. The purpose of the study is to gain a greater understanding of the barriers and facilitators of help-seeking behaviors among male survivors of military sexual trauma. Findings from the study will inform the development of recommendations to improve sexual assault reporting policies and practices and to increase access to support resources.

The duration of participation is 60 minutes on one occasion.

There will be about 20 people taking part in the study over a period of one year.

3. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, the researchers will confirm with you if you are eligible for the study. Eligible participants will be at least 18 years old, must identify as a man, be either active duty Sailors or U.S. Navy veterans who discharged within the last 2 years, and have experienced sexual trauma (i.e., unwanted sexual contact or sexual harassment) during their time in military service. In addition, eligible participants must not be involved in any current legal proceedings involving military sexual trauma.

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

You will be asked to provide your voluntary consent to participating in this study if you meet the eligibility criteria described above.

If you meet the eligibility criteria, you will be asked to take part in a remote one-on-one phone interview. The interview will take no longer than 60 minutes to complete. In the interview, you will be asked to talk about your experiences with unwanted sexual contact or harassment during military service and you will be asked to talk about your decision-making processes and help-seeking behaviors following unwanted sexual contact or harassment. You will be asked whether you talked to other people about your experiences, or whether you sought support from different individuals.

You will not be identified as a participant in this study. The interview will be audio recorded with your consent and then transcribed to make sure we do not miss any information you provide. Audio files will be deleted after they are transcribed. All transcripts will be digitally secured and only accessible by research staff.

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

Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information you provide in the interview.

Though unanticipated, there is a risk that the interview content may cause temporary discomfort or emotional distress. You do not have to answer any questions that make you feel uncomfortable. If you experience distress, please contact the Principal Investigator of this study using the contact information provided in section 21 of this document. You will also be provided with a list of support resources you may access on your own should you choose to do so.

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. The possible benefit to others is a potential improvement to Department of the Navy sexual assault response policies and programs.

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 an electronic $40 Amazon gift card code.

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):

Kristen Walter, PhD
kristen.h.walter.civ@health.mil
(619) 553-0546

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

12. SOURCE OF FUNDING:

Department of the Navy Office of Force Resiliency.

13. LOCATION OF THE RESEARCH:

This study is being conducted by researchers at the Naval Health Research Center in San Diego, CA.

14. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

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

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, 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: No names or identifying information are required as part of the activities in study. Your personal email address and/or phone number are the only potentially identifying information that will be requested and will be used only to schedule the individual interview. This contact information will be securely stored separately from study data and will be destroyed once you have completed the interview.

If you choose to participate, you will be asked to complete an interview, during which you may be asked to discuss your personal experience of sexual assault or harassment. To protect your confidentiality during the interview, we will ask you not to use your name or any other identifying information, including your rank or title. For remote participation, we recommend that you find a private room where you will be comfortable participating without being overheard by others. When the audio recordings of the discussions are transcribed, any potentially identifying information, such as names and locations, will be redacted from the written transcripts. Once transcription has been completed and verified, all audio files will be permanently destroyed.

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

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. LONG TERM USE OF DATA

The data collected as part of this research will not be used or distributed for future research studies.

17. USE OF INFORMATION AND SPECIMENS

The information collected as part of this research will not be used or distributed for future research studies.

18. 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.

19. 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 the research study after beginning the interview, 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.

The principal investigator of this research study may terminate your participation in this research study at any time if he 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.

20. 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 Walter, PhD
Phone: (619) 553-0546
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 by phone at (619) 553-8424 or usn.nhrc.irb@health.mil.

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE PROVIDING CONSENT. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.
A copy of this document will be given to you.

☐

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 boxes below, I have not given up any of my legal rights as a research participant.

☐ Yes, I agree to participate in this study.

☐ I understand that the interview will be audio recorded and I provide my consent to be recorded.

FOR ACTIVE DUTY SERVICE MEMBERS:

☐ I attest that I will participate in this study while in off-duty, liberty or leave status.