Meets 2018 Common Rule Requirements

Naval Health Research Center
CONSENT TO PARTICIPATE IN RESEARCH
Title: *Challenges of Operation Environments (COPE) Study*
Principal Investigator: *Cameron McCabe, 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.

1. **KEY INFORMATION:**

This study includes the use of surveys or questionnaires.
OMB Control #: 0703-0100
Survey Expiration: 30 NOV 2027

The purpose of this study is to learn more about the stressors experienced by Sailors. We are specifically interested in stressors experienced by Sailors and are seeking volunteers. This study was funded by the Defense Health Agency because they want to learn about specific factors that affect the health, performance, and readiness of Sailors. This study is being conducted by researchers at the Naval Health Research Center in San Diego, California. Up to 86,200 people will take part in this study across several sites. Up to 6,000 will be asked to participate in discussions with study staff. Participation in this research study is completely voluntary. If you have any questions, do not hesitate to ask them.

If you agree to participate, you will be asked to spend about 30 minutes completing an anonymous questionnaire about your health, readiness, and experiences at this Command. You will complete this questionnaire in one of three ways: (1) electronically, on a tablet loaned to you by the study staff; (2) electronically, on a personal computer, using a weblink provided by study staff, or (3) on a hard copy (paper) survey provided by study staff. Study staff will announce which of these options is relevant to you during the consent process. No personally identifying information will be collected on the questionnaire. Sailors who participate in person while off duty will receive a $15 gift card to thank them for their participation. After completing the questionnaire, you will receive the giftcard if you can attest that you were off duty while you completed it.

Additionally, you may be asked to talk to one of our staff for 60 to 90 minutes in one, or both, of two different types of focus groups. The first focus group is about your experiences

at this Command and how they impact your mental health and well-being. The second focus group is designed for leaders who are involved in the implementation of programs and policies to improve Command climate. These discussions will take place in a group setting with several other service members who are also participating. In the discussion, a researcher will ask the group approximately 15 open-ended questions. At the end of the discussion you will also be asked to spend about 5-10 minutes filling out a questionnaire about your personal characteristics and experiences. No personally identifying information will be collected during the discussion or on the questionnaire. If you participate in the focus group about experiences that impact mental health and well-being in person and while you are off duty, you will be offered a $40 gift card to thank you for your participation. If you participate in the focus group about implementation of programs and policies in person and while you are off duty, you will be offered a study challenge coin to thank you for your participation. You can still participate if you are on duty with appropriate permission from your command, but you will not be able to receive a monetary incentive. Participants who participate in remote data collection will not be eligible for gift card incentives for survey completion.

There are no direct benefits to you for participating; however, the information learned from this research study may help researchers improve the training, programs and services provided to Sailors.

The investigators believe that the risks or discomforts to you from participating in this study are minimal and include psychological discomfort and accidental disclosure of your information. The questionnaire includes questions about your health and your experiences at this Command, which may include experiences on deployment or during field training operations at sea; if you feel uncomfortable answering any of the questions you can decline to answer the question or end your participation completely. If you feel particularly upset by any portion of this study, we encourage you to call your regular healthcare provider or chaplain.

Several safeguards are in place to minimize the risk of accidental disclosure of your information. For example, to protect your privacy and information, we will not collect your name or other identifying information as part of your participation, and we will store all study data on secure servers at the Naval Health Research Center. We may ask for your first name and phone number if you choose to volunteer to participate in the telephone interview, but we will destroy that information once the interview is complete. If you participate in a discussion with study staff we will ask you, and other participants, to refrain from using any identifying information such as names during the discussion. A full description of all safeguards is provided below under “What health information will be collected and will it be kept confidential?”

There may be other risks, which are unknown at this time.

If you decide to take part in this research study, you will be asked to indicate your consent to participate by checking a box on this document. Before you check this box, 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 who has unique knowledge about challenges Sailors experience that may affect their health, performance, and readiness. As you can imagine, we are more effective as researchers and health care professionals if we learn from you what you are experiencing. The primary purpose of this study is to learn about how challenges experienced may affect the health and readiness of sailors. We are particularly interested in learning about what can cause stress and health problems and potentially reduce performance in Navy environments. If you agree to participate, you will be asked to spend about 30 minutes outside of working hours completing an anonymous questionnaire either on a tablet, on the internet, or on paper.

You may also be invited to participate in a 60-90-minute conversation in a group setting about your experiences at this Command or your experiences with implementing programs and policies to improve Command climate. During this discussion you will be asked about 15 questions.

There will be up to 86,200 people taking part in the study from multiple Commands over the course of a year. Up to 6,000 people will be asked to participate in focus group.

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

If you agree to participate, you will be asked to spend about 30 minutes outside of working hours completing an anonymous questionnaire. No identifying information will be collected on the questionnaire. If you are off duty you will be offered a $15 gift card to thank you for participating in the survey. You may also be asked to participate in a 60- 90-minute discussion with one of our research staff in a small group of other Sailors. You will be offered a $40 gift card for participating in the discussion about experiences and/or a study challenge coin for participating in the discussion about implementation if you participate while you are off duty. No identifying information will be collected during this discussion.

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

The questionnaire and discussion include questions about your health and your experiences while working at this Command; if you feel uncomfortable answering any of the questions you can decline to answer the question or end your participation completely. If you feel particularly upset by any portion of this study, we encourage you to call your regular healthcare provider or chaplain.

Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information researchers have stored about you. Several safeguards are in place to minimize the risk of accidental disclosure of your

information, including labeling all data with a unique numeric code instead of personally identifiable information, and storing all data on secure servers at the Naval Health Research Center. We may ask for your first name, phone number, and/or personal email address to send you a gift card code or if you choose to volunteer to participate in the interview or focus group discussion, but we will destroy that information once the discussion is complete. If you participate in a discussion with study staff, we will ask you, and other participants, if applicable, to refrain from using any identifying information such as names during the discussion. A full description of all safeguards is provided below under "What health information will be collected and will it be kept confidential?"

There may be other risks that we do not yet know about.

5. **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. For example, the information from this research study will help researchers improve training, programs and services provided to Sailors.

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

   Participation in this study is voluntary, you do not have to participate in this research.

7. **IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?**
   Yes, for your participation, you will receive: a $15 gift card for the questionnaire. If you volunteer and are selected to participate in a discussion with study staff, you will receive an additional $40 gift card for the discussion about experiences and/or a study challenge coin for the discussion about implementation. You will only be eligible to receive incentives if your participation occurs in person and while off duty.

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):**
   Dr. Cameron McCabe at (619) 553-8067 or cameron.t.mccabe.civ@health.mil.

10. **STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):**
    This study is being conducted by 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.

11. **SOURCE OF FUNDING:**

This research was funded by a grant awarded by the Defense Health Agency and the Office of Naval Research.

12. **LOCATION OF THE RESEARCH:**

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

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 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 it online at:
https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2005.pdf

Federal regulations give you certain rights related to your personal information. If you choose to be in this study, the study staff will obtain the following information about you, including information that will identify you (first name, cell phone number, and personal email address). Please note that no personal health information will be collected as part of this study.

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 inspection of your research records to ensure that the rights and safety of all 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: using a study identification number instead of a name or other identifying information on study data; never linking study data with potentially identifying information; destroying any potentially identifying information as soon as gift card codes have been delivered; storing all data on password-protected, secured servers at the Naval Health Research Center.

You will be asked to take a questionnaire that will contain questions about your personal and professional experiences in the military. You may also be asked to participate in a discussion. In the discussion, you will be asked not to use your name or other identifying

information. However, if you do, all identifying information will be redacted from the audio transcripts; also, all audio files will be permanently deleted as soon as they are transcribed. The questionnaires will not include identifying information and all of the data we collect from you will be kept private and confidential so that none of your responses can be linked back to you as an individual.

The Principal Investigator is responsible for storing all information collected about you during the study. This information will be protected by storing all electronically collected data in password protected files, on password protected computers, on the secure computer network at the Naval Health Research Center. All files that may identify you (i.e. contact information such as phone numbers and email addresses) will be stored separated from your study data so that it will not be possible to link your study data to your contact information. Your contact information will be destroyed or deleted within one month after data collection for the study is completed.
Access to all data will be limited to staff involved in this study and will not be shared with any other organizations.

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

If you participate in a focus group discussion we also ask that each of you respect the privacy of everyone in the group and not share or repeat what is said during the discussion in any way that could identify anyone here. However, since someone in the group may not obey instructions to keep all comments confidential, we recommend that you avoid saying anything that you don't want to be repeated outside the group. We ask your cooperation in protecting the privacy of the comments made within this session by not saying anything that would identify you or other participants.

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. 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.

16. **Long Term Use of Data**

The Principal Investigator has requested to save selected data collected from your participation in this study for use in possible future research. Since all stored data will have no identifying links, the data is unable to be linked back to a specific participant. By

consenting to take part in this effort, you are also agreeing for the future use of your data as outlined in this consent. This future research may be in the same area as the original study or it may be for a different kind of study.

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

Should you choose to withdraw, you must write to the Principal Investigator. If you do not follow these procedures, you will still be considered an active participant in the study. If you decide to no longer participate in this research study, no new information about you will be gathered after that date and you may no longer be allowed to participate in the study. Information that has already been gathered may still be used and, because all of your data will be collected anonymously, there is no way to guarantee that it can be removed from the electronic database for this study.

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: Dr. Cameron McCabe
Phone: (619) 553-8067
Mailing Address: 140 Sylvester Rd. San Diego, CA 92106

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 619-553-8424 or email usn.nhrc.irb@health.mil.

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE CONSENTING TO PARTICIPATE IN THIS STUDY. 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.

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.

☐ Mark this box if you agree to participate _____ Date

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

_____ _____
Printed Name of Administering Individual Date

_____ _____
Signature of Administering Individual Date