**Naval Postgraduate School**

**Consent to Participate in Research**

**Introduction.** You are invited to participate in a research study entitled*add name of study***.** The purpose of the research is *give an explanation of the purposes of the research*. This research study is about *give a concise teaser/statement of the study (ex. This is a survey/interview/experiment/study about your mood/behaviors/exercise tolerance/sleep patterns...and you will be asked to wear heart rate monitor/ring/glasses/complete a 10 page survey.*

**Key Information.**

1. Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you would otherwise be entitled, and you may discontinue participation at any time without penalty or loss of benefits to which you otherwise would be entitled.
2. *List reasonably foreseeable risks or discomforts to prospective subjects. When research involves risks to their fitness for duty state,* ***“This study involves risks to your fitness for duty. You should seek command guidance before participating.”***
3. *Describe benefits to the DOD, any indirect benefits to the prospective subjects, and any benefits to others that may reasonably be expected from the research.* You will not directly benefit from participating in this study*.*
4. Up to *xx* number of individuals will participate in this study. The alternative to participating in this study is to not participate*. Add the duration of the subject’s participation (ex. No more than 3 hours over the course of the day, 1.5 hour lecture and up to 1.5 exercising, no more than 100 days – divided into three roughly 30 day increments, etc.)*
5. *Add a description of the requirements for participation in the study, e.g., time for participation (on/off on-duty), additional individual permission from unit commander for participation, etc.*
6. There is no cost to participate in this research study. You will not be paid for your participation.

Study Procedures*:*

* + *a* ***highly detailed*** *description of the procedures the subjects will follow,*
	+ *identify any procedures which are experimental (e.g., if subjects will be exposed to different experimental conditions),*
	+ *state which, if any, procedures are new or untested, state that the procedure(s) are only related to the research and serve no purpose other than this research endeavor.*
	+ *State whether participants will be audio or video recorded. If audio or video recording, state the purpose for the recording and what will be recorded.*
	+ *Statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.*
	+ *If research is more than minimal risk, provide explanation as to whether medical treatments are available if injury occurs and if so, what they consist of.*
	+ The interview/survey/experiment will take place *state where the research will take place. If an exact location is not available describe the characteristics of the location/environment).*

**Confidentiality & Privacy Act.** Any information that is obtained during this study will be kept confidential to the full extent permitted by law. All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. *[Insert a description of how records and data will be stored and maintained and who will have access. Describe any study specific issues that may increase the risk of breach of confidentiality.]*

However, it is possible that the researcher may be required to divulge information obtained in the course of this research to the subject’s chain of command or other legal body. *Describe what type of information you might be required to divulge/disclose, who might be notified, and the process for notification.*

**Research data can be requested by NPS HRPP, IRB, or DoD higher level reviewers as part of their duties.**

*The information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.*

*Or*

*Is it a possibility that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative.*

*If you will potentially quote subjects in your research products (thesis, technical reports, etc.), include this language:*

If you consent to be identified by name in this study, any reference to or quote by you will be published in the final research finding only after your review and approval. If you do not agree, then you will be identified broadly by discipline and/or rank, (for example, “fire chief”).

[ ]  I consent to be identified by name in this research study.

[ ]  I do not consent to be identified by name in this research study.

**Points of Contact**. If you have any questions or comments about the research, or you experience an injury or have questions about any discomforts that you experience while taking part in this study, please contact the Principal Investigator, *Dr. Joseph Researcher, 656-9999,* *jresea@nps.edu**.* Questions about your rights as a research subject or any other concerns may be addressed to the Navy Postgraduate School IRB Chair, Bryan Hudgens, (831) 656-2039, bryan.hudgens@nps.edu.

***For studies with a reporting plan, add contact info for those people in this section as well (Chaplain, DoD suicide prevention number, 988 etc.) so that participants could self-report.***

**Statement of Consent**. I have read the information provided above. I have been given the opportunity to ask questions and all the questions have been answered to my satisfaction. I have been provided a copy of this form for my records and I agree to participate in this study. I understand that by agreeing to participate in this research and signing this form, I do not waive any of my legal rights.

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Signature of Participant Date

***Additional Elements of Informed Consent: you must add these elements to the body of your consent form when applicable or delete the entire section before submitting this form to the IRB for review.***

1. *A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.*
2. *Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent.*
3. *Any additional costs to the subject that may result from participation in the research.*
4. *The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.*
5. *A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.*
6. *A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.*
7. *A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.*
8. *For research involving biospecimens, state whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).*