U.S. Army Aeromedical Research Laboratory

CONSENT TO PARTICIPATE IN RESEARCH

Title of Protocol: Sustaining Aviator Performance during Extended Operational Flight

Principal Investigator: Katie Feltman, Ph.D.

You are being asked to participate in a research study. As you think about your decision, you should consider all of the information in this informed consent form.

The table below summarizes some key things to think about. After reading this summary, if you think you might be interested in participating, read the rest of the form for more details about the study.

RESEARCH SUMMARY	
Voluntary Participation	You do not have to take part in this research. It is your decision. You can choose to stop participating at any time during the study.
Purpose	This research will help us decide whether non-invasive brain stimulation can be used to sustain aviator performance, specifically as it relates to maintaining attention.
Duration	About 16 hours over the course of 4 days, including today.
Procedures	While you are in the study, you will: • Complete questionnaires, computer tasks and flights in the Black Hawk simulator. • Receive **electrical stimulation** through electrodes on your scalp. • Wear a physiological measurement device.
Eligibility	• **Must** be a male in good health – current DD-2992 • **Must** have at least 200 hours flight experience **and** flown within the past 6 months • **Must** have a minimum of **6 hours of sleep** the night before each test session • **Must** be able to perform to flight standards • **Avoid** over the counter **medications** which may cause drowsiness **minimum 16 hours** before each test day • **Avoid nicotine** a **minimum of 2 hours** before each test day • **Avoid stimulants including caffeine** a **minimum of 16 hours** before each test day • **Avoid alcohol** a **minimum of 24 hours** before each test day
Drugs/Devices	The device used in this study is the transcranial direct current stimulator. It is not FDA approved. It is used for investigational purposes only in this research.

Risks	The **main** risks from being in this study are: • Tingling or itching below the electrodes • Headache • Fatigue or drowsiness • Redness of the skin below the electrodes • Slight risk of skin burns below electrodes • Discomfort in answering some questions in the questionnaire packet. • Discomfort and fatigue during tasks. • Discomfort wearing physiological measurement device. *Steps to lessen the risks are described later in this consent form.
Benefits	There is no benefit to you from participating in this study.
Payment	You will be paid for your participation in this study. You must be on leave.

INTRODUCTION

You are asked to participate in a research study conducted at the United States Army Aeromedical Research Laboratory (USAARL) by Katie Feltman, PhD, the Principal Investigator and a Research Psychologist at USAARL. You are asked to participate in this research because you are a rated aviator and consider yourself to be in good health condition. This study will use non-invasive brain stimulation to test whether it can help you maintain attention during a flight task. The device that we are using has previously been used to assess performance changes during attention, memory, and learning tasks, and has been found to be safe.

You do not have to take part in this research. It is important that you understand this research study so that you can make a decision. This process is called informed consent. To make your decision, you will need to consider all of the information provided here and ask questions about anything you do not understand. You may want to talk with your family, friends, or others to help you decide if you want to be part of this study. When you feel that all of your questions have been answered, you will be asked if you agree to be part of the research or not. If you agree, you will be asked to sign this consent form. You will be given a copy of this form to keep.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this research is to use a device called a transcranial direct current stimulator, which we will show you in a moment, to stimulate the brain through the application of a low-intensity electrical current that is applied through your scalp. You may have heard about this type of device being used to enhance video game playing performance or even seen it for sale on commercial websites, such as Amazon. We are using the device to test whether it can help aviators maintain attention and performance during simulated flight, and whether the effects of stimulation impact sleep. We will also measure changes to brain activity that occur after applying stimulation.

This research will help us decide whether non-invasive brain stimulation can be used to maintain aviator performance. The device we are using is certified by the European equivalent of the Food and Drug Administration (FDA). The device is not approved by the FDA and is therefore an investigational medical device. The study is a single blind study, which means you will not know

whether you are receiving an active stimulation or sham stimulation, but members of the research team will know. Sham stimulation is like a placebo, we turn the stimulation on for a short duration and then turn it off again. We do this so that you cannot tell if you are in receiving the active or sham stimulation.

WHAT WILL HAPPEN DURING THIS RESEARCH?

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If you agree to participate in this research, you will be asked to do the following things:

Session 1: (total time for this day = approximately 5 hours)

- You will meet with a study physician who will ask you questions about your medical history. If eligible to participate, you will be enrolled in the study. Your temperature, blood pressure, respiration rate, pulse and oxygen saturation will be measured.
- You will be given an Actiwatch (like a Fitbit) to wear the entire time you are in the study. This will monitor your sleep.
- Complete maneuvers in the Black Hawk simulator to determine whether you can meet the flight standards for the study.
- Complete 14 questionnaires about attention disorders, intelligence, motivation, sleep habits and preferences, depression symptoms, vision, mood, personality, and susceptibility to boredom.

  Experience 5 minutes of the stimulation so you may become familiar with how it feels when applied.

Sessions 2 & 3: Experimental testing (total time for these days = approximately 5.5 hours per day)

- At the beginning and end of each of these days we will measure your temperature, blood pressure, respiration rate, pulse and oxygen saturation.
- Complete 8 questionnaires about side effects, mood, sleepiness, depression, mental workload, and use of the stimulation.
- Measure EEG before and after simulated flight.
- Complete 2 mental tasks on a computer that will look at your attention.
- Complete a simulated flight.
- Receive active or sham transcranial direct current stimulation for a total of 20 minutes.
- Recreational time for 1 hour at the end of the day to ensure your safety.
- At the end of the hour a study physician will meet with you to confirm that it is safe for you to be released.

Session 4: Final questionnaires and return actiwatch (total time for day = approximately 15 minutes)

- Return Actiwatch to USAARL.

- Complete 3 questionnaires to measure sleepiness and sleep habits, and perception of usefulness of transcranial stimulation.
- Complete tax form for payment.

HOW LONG WILL I BE IN THE STUDY?

4 days total for approximately 16 hours.

WHAT PRECAUTIONS DO I NEED TO TAKE DURING THE STUDY?

- Must have at least 6 hours of sleep the night before each test session
- Avoid taking over-the counter-medications which may cause drowsiness for a minimum of 16 hours before each test session
- Avoid all nicotine consumption for a minimum of 2 hours before each test session
- Avoid using any stimulants including caffeine for a minimum of 16 hours before each test session
- Avoid consuming alcohol for a minimum of 24 hours before each test session

**A sheet detailing these precautions will be given to you after you are enrolled in the study.*

HOW MANY PEOPLE WILL BE IN THE STUDY?

We plan to have 32 individuals participate in this study.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Risks of Electrical Stimulation

The current literature suggests few risks in using transcranial direct current stimulation. A current strength of 2 mA in considered safe and is what will be used in this study. A recent test applied 10 mA of transcranial direct current stimulation to a cadaver for a full hour and found that while there were significant burns to the skin, there was no damage to brain tissue. To ensure your safety you will be monitored closely for adverse effects during stimulation and at least one hour after stimulation. Currently it is suggested that there are no long-term effects associated with this stimulation, however, long-term effects have not been thoroughly studied, so there may be unknown risks.

Literature suggests there are several minor side effects that have the probability of occurring from receiving this stimulation and they typically go away shortly after the stimulation has stopped:

- Tingling or itching below the electrodes
- Headache
- Slight risk of skin damage or irritation (much like sunburn)
- Redness of the skin below the electrodes
- Skin burns when electrodes are not properly applied
- Short duration of warming sensation on the scalp
- Fatigue or drowsiness

Literature also suggests the possibility of a few other side effects, but these are even less likely to occur (less than 1% chance). These are:

- Mood changes, to include hypomania (extreme feelings of happiness, hyperactivity)
- Nausea

Precautions: While we cannot protect you from the occurrence of side effects, we can be prepared for them. One or more research technicians will be with you throughout the study. A study physician will be present in the laboratory until the time you are released to go home. Please notify a research team member immediately if you start experiencing any adverse effects.

Risks of Wearing the EEG

An additional risk is that you may become uncomfortable while wearing the EEG. If you become uncomfortable wearing the EEG at any time, please let a technician know and we will remove or adjust the system. If you wish to discontinue you will be able to do so at any time.

Risks of Answering Questionnaires

Another additional risk of this study is that you may feel uncomfortable answering some of the questions in the questionnaire packet. The questionnaires will ask questions related to depression and anxiety symptoms as well as substance use. You are allowed to skip any questions you do not wish to answer. If you indicate that you are a danger to yourself (suicidal) or others, the study physician will review and verify your responses with you, and if accurate, a member of the research team will accompany you to the Lyster Army Health Clinic's Behavioral Health Clinic for further evaluation and assessment. Your chain of command would be notified in such an event.

If you are feeling distressed or hopeless, thinking about death or wanting to die, or, if you are concerned about someone who may be suicidal, please contact Suicide Prevention Lifeline at 1-800-273-TALK (8255). If you feel concerned about your alcohol or substance use, please contact the Army Substance Abuse Program at Fort Rucker at (334) 255-7905

WHAT ARE THE POSSIBLE BENEFITS FROM BEING IN THIS RESEARCH?

There are no benefits to you from participating in this study. Your participation will contribute to the medical knowledge and scientific investigation of possible uses for this type of stimulation in a military population.

WILL RESEARCH RESULTS BE SHARED WITH ME?

No results of this study will be provided to you.

WHAT ARE MY OTHER OPTIONS IF I DO NOT PARTICIPATE IN THIS STUDY?

There are no other options available to you for this study at this time if you choose to not participate.

WILL I HAVE TO PAY FOR ANYTHING IF I TAKE PART IN THIS RESEARCH?

You will be responsible for your own transportation to and from USAARL. Drinks and snacks will be provided throughout the study. You may bring your own drinks, snacks, and lunch if you prefer, however, you will not be allowed any caffeine until after the testing session is complete.

WILL I BE PAID TO TAKE PART IN THIS RESEARCH?

You must be in an off-duty status to be compensated for participation in this study. If you participate during duty hours, you must have the consent of your cadre or supervisor and will not be able to receive compensation. If you participate during approved leave you will need to provide written or verbal confirmation that you are on approved leave. If you are participating outside of duty hours, you will need to provide written or verbal confirmation that you are off-duty. You will be compensated $1,500 for completing this study. You will receive $500 for each experimental testing day, including today (sessions 1 – 3). If you choose to withdraw from the study after completing today's testing, you will receive $500. If you choose to withdraw following session 2, the second full day of testing, you will receive $1,000. It is important for you to note that you will need to report this as personal income on your next income tax return and will need to complete a tax form to receive compensation this includes providing your social security number (SSN) to process the payment, as required by law. Your SSN will be carefully protected and total payments of $600 or more within one calendar year will need to be reported by to the Internal Revenue Service (IRS).

WHAT HAPPENS IF I AM INJURED AS A RESULT OF TAKING PART IN THIS RESEARCH?

If you are injured because of your participation in this research and you are a DoD healthcare beneficiary (e.g., active duty military, dependent of active duty military, retiree), you are entitled to medical care for your injury within the DoD healthcare system, as long as you remain a DoD healthcare beneficiary.

If you are injured because of your participation in this research and you are not a DoD healthcare beneficiary, you are entitled to care for your injury at DoD hospitals or clinics, but care for your injury may be limited to a given time period, and your insurance may be billed. It cannot be determined in advance which DoD hospital or clinic will provide care. If you obtain care for research-related injuries outside of a DoD hospital or clinic, you or your insurance will be responsible for medical expenses.

For DoD healthcare beneficiaries and non-DoD healthcare beneficiaries: Transportation to and from hospitals or clinics will not be provided. No reimbursement is available if you incur medical expenses to treat research-related injuries. No compensation is available for research-related injuries. You are not waiving any legal rights. If you believe you have sustained a research-related injury, please contact the Principal Investigator (Dr. Katie Feltman, 334-497-4512).

HOW WILL YOU PROTECT MY PRIVACY AND THE CONFIDENTIALITY OF RECORDS ABOUT ME?

The PI will keep records of your participation in the research. To protect your privacy questionnaire responses, medical screening, and performance on the mental and military tasks, will be labeled or "coded" with an assigned number and kept in a locked filing cabinet in a locked office. This number will not include your name or social security number. The PI will

keep the link between your participant number and your name in a locked office on a password-protected computer. The principal and associate investigators are the only people who will be able to match your research participant number with any of your personal identifying information. This link will be destroyed at the completion of the study. In the event of a medical emergency or adverse reaction, the study physician will be able to identify which stimulation you received (active or sham).

Paper copies of data will be kept for a minimum of 3 years after the closure of the study. Electronic copies of your de-identified data will be kept indefinitely. Your data may be used for future research studies or given to other researchers for future research studies without your permission to do so. In these cases, only your de-identified data will be available.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity to others. Authorized representatives of the following groups may need to review your research and/or medical records as part of their responsibilities to protect research participants:

- U.S. Army Medical Research & Development Command Institutional Review Board
- DOD and other Federal offices charged with regulatory oversight of human research
- U.S. Army Aeromedical Research Laboratory Regulatory Compliance Office
- USAARL Safety Manager
- Food and Drug Administration

Complete confidentiality cannot be promised for military personnel, because information bearing on your health may be required to be reported to appropriate medical or command authorities.

It is the policy of the U.S. Army Medical Research and Development Command that data sheets are to be completed on all volunteers participating in research for entry into this Command's Volunteer Registry Data Base. The information entered into this confidential data base includes your name, address, Social Security number, study name and dates. The intent of the data base is two-fold: first, to readily answer questions concerning an individual's participation in research conducted within the USAMRDC; and second, to ensure that the USAMRDC can exercise its obligation to ensure research volunteers are adequately warned (duty to warn) of risks and to provide new information as it becomes available. The information will be stored at USAMRDC for a minimum of 75 years.

WHAT IF I DECIDE NOT TO PARTICIPATE IN THIS RESEARCH?

It is your choice whether you want to participate in this research. You can choose not to be in the study now or stop taking part in this research at any time without any penalty or loss of benefits to which you are entitled. Deciding not to participate now or withdrawing at a later time does not harm, or in any way affect, your future relationships with USAARL.

If you choose to withdraw from the study, you will only be compensated for the days in which you participated, as explained on page 5. If you withdraw from the study, the data collected up to the point of your withdrawal will still be used for analysis. If you decide to withdraw from the study after you receive transcranial stimulation, for your safety a study physician will assess you before releasing you from the study.

WHAT COULD END MY PARTICIPATION IN THE RESEARCH?

The investigator may withdraw you from participating in this research if circumstances arise which warrant doing so. These circumstances may include: if you are unable to complete the tasks, if it is determined that it is in your best interest to stop your participation in the study, if questionnaire data suggests that your answers are not reliable (this is determined after your participation), or if your questionnaire responses indicate you are very depressed or a threat to yourself. The investigator will make the decision and let you know if it is not possible for you to continue.

WHO SHOULD I CALL IF I HAVE QUESTIONS OR CONCERNS ABOUT THIS RESEARCH?

If you have questions about the research at any time, you should contact Dr. Katie Feltman 334-497-4512; kathryn.a.feltman.civ@mail.mil.

If you have questions regarding your rights as a research participant you may contact the HQ USAMRDC IRB Office at 301-619-6240 or by email to usarmy.detrick.medcom-usamrmc.other.irb-office@mail.mil.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law.

By signing below, I agree that I have been provided time to read the information describing the research study in this 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.

SIGNATURE OF RESEARCH PARTICIPANT

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

SIGNED CONSENT OBTAINED/RECEIVED BY:

_____ _____
Printed Name Date Received