Cranial Electrotherapy Stimulation on Acute Stress

Page 2-9: Civilian Participant Informed Consent Form – IRB Approval Date: April 19, 2023

Page 10-17: Soldier Participant Informed Consent Form – IRB Approval Date: April 19, 2023

TUFTS UNIVERSITY
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title of the Study: Cranial Electrotherapy Stimulation (CES) Influences on Acute Stress Reponses
Principal Investigator: Kano Okano, Ph.D., Tufts University, Center for Applied Brain and Cognitive Sciences
Phone: 617-627-1059
Email: kana.okano@tufts.edu

You are being asked to volunteer in a research study. Please find below information about this research for you to carefully consider when deciding about whether or not to participate. Please ask questions about any of the information you do not understand before you decide whether to participate.

Key Information for You to Consider
Statement of Research You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation. **Purpose**. The purpose of this research is to evaluate whether cranial electrotherapy stimulation (CES) can be used to reduce your body's stress response. **Duration.** It is expected that your participation will last from 4 to 6 weeks. **Procedures and Activities.** You will be asked to participate in 22 visits to the laboratory. The first and last visits will assess your performance on a series of tasks while we monitor your hormones, heart and breathing rate, emotional stress, and cognitive performance. Between the first and last visits, you will participate in 20 sessions of CES, once per day over the course of 4-6 weeks. We are interested in whether CES changes your stress responses and ability to perform tasks under stress. **Risks:** The risks or discomforts associated with this research include temporary dizziness, vertigo, headache, nausea, lightheadedness, and/or skin irritation when receiving CES. There is also a risk of developing skin irritation when receiving torso shocks, including temporary redness, rash, itching, and/or peeling. **Benefits:** There are no direct benefits to you for participating in this research. However, we anticipate that the study results will help the research community understand whether CES can reduce your body's responses to stress.

What is this study about?
Researchers at Tufts University are conducting a study on whether cranial electrotherapy stimulation (CES) can be used to reduce your body's stress response. You will be asked to participate in 22 visits to the laboratory. The first and last visits will assess your performance on a series of tasks while we monitor your hormones, heart and breathing rate, emotional stress, and cognitive performance. Between the first and last visits, you will participate in 20 sessions of CES, once per day over the course of 4-6 weeks. We are interested in whether CES changes your

stress responses and ability to perform tasks under stress. You are one of up to 100 participants to take part in this study. The study is supported by the U.S. Army DEVCOM Soldier Center (Natick, MA) who is sponsoring this research.

What will happen during this research?
If you agree to be in this research, your participation will include the following:

1. Visit the Center for Applied Brain and Cognitive Sciences (CABCS; Medford, MA) at Tufts University for a *baseline testing session* that will last about 3 hours. During this session, we will ask you to:
    a. Fill out questionnaires asking you about your demographics, emotions, and sensations.
    b. Complete a two-minute CES thresholding procedure. This involves placing ear clips onto your earlobes and slowly increasing the strength of the CES until you feel uncomfortable (such as feeling dizzy, lightheaded, vertigo, nausea). This procedure will make sure the strength of CES received during all sessions will be individualized and not uncomfortable. If you cannot tolerate a minimum intensity of CES, you will be dismissed from the study.
    c. Provide several saliva samples by placing a small piece of gauze under your tongue for 2 minutes.
    d. Learn and be tested on your memory for suspicious objects, a map, and your ability to distinguish enemies versus friendlies.
    e. Wear a chest strap that monitors heart rate and breathing, a pair of eye tracking glasses, and a waist strap that delivers uncomfortable and stressful electric shock.
    f. Complete a series of tasks in virtual reality that involve you detecting suspicious objects, pointing towards locations, and distinguishing enemy from friendly targets. You will use a simulated M4 rifle to shoot targets and make responses during these tasks. When your responses are incorrect, you will receive an uncomfortable electric shock to your waist.
    g. Learn about the daily CES sessions (more information is below).
2. Visit the laboratory at CABCS for *20 CES sessions, one per day*. These sessions will be held during weekdays (M-F) and each session lasts about 40-60 minutes. During each session, we will ask you to:
    a. Complete a daily checklist and emotion questionnaire.
    b. Wear earlobe clips and electrodes that will provide you with either Active (real) or Sham (fake) stimulation from the CES device for 20 minutes. During this time, you will be asked to sit and relax.
    c. After stimulation is finished, we will ask you to complete an emotion questionnaire again, as well as a side effects checklist.

3. Visit the laboratory at CABCS for a *follow-up testing session* that will last about 3 hours. During this session, your experience will be the same as in the *baseline testing session* (detailed above).

During the 20 daily CES sessions, we will use either an Active or Sham CES device, depending upon which group you are randomly assigned to. You and the experimenters will not know whether you are receiving active or sham CES.

The Active CES device used in this study (the Alpha Stim) is cleared by the U.S. Food and Drug Administration (FDA) for the treatment of anxiety, insomnia, and depression. Because our study is using the device with healthy participants, the device is being used in a manner that is for *investigational use only*. This means that the device is being used in a study examining its safety or effectiveness, and not for the treatment, diagnosis, or prevention of any disorder.

What will you do to protect my privacy? The researchers will make every effort to prevent anyone who is not on the research team from knowing that you provided information, or what the information is. Responses will not include names and will be presented to others only when de-identified and included with other responses.

Representatives of the Tufts Social, Behavioral, & Educational Research Institutional Review Board (Tufts SBER IRB) and the U.S. Army Human Research Protections Office (AHRPO) (or the DOD) are authorized to review the research records. No HIPAA information will be recorded in the current study. However, if it was, representatives of Tufts SBER IRB and AHRPO are a party to whom private health information may be disclosed, if such information were to be recorded as part of the study.

In addition to the funding agency's Human Research Protection Program Office, authorized representatives of the following groups may need to review your study related information as part of their responsibilities to protect research participants:

- The Research Study Team
- The U.S. Army Human Research Protections Office (AHRPO, Department of the Army's regulatory agency that oversees human subject research)
- Tufts University Social, Behavioral, and Educational Research Institutional Review Board
- Tufts University Audit and Management Advisory Services

In order to maintain confidentiality and to avoid loss of privacy, we will assign unique codes to your data that will not contain any personally identifiable information. Only the Principal Investigator (PI) will have access to a master list and a key that matches you to the coded data (all data collected from you, including questionnaire responses, and logged behavioral data). This key will be kept locked on a password-protected computer or server.

All study data that we collect from you will be locked up or kept on password-protected

computer files and servers. When the study is closed and we have analyzed and verified all of the data, the consent forms and any documents that link your identity to your data will be destroyed after three years. If any reports and talks are given about this research, we will not use your name or identify you in any way.

This study may optionally involve recording video and/or taking photographs of you performing tasks. If you agree to have these collected, digital videos and/or photographs would be used for educational, reporting, or illustration purposes and will be stored indefinitely. The Principal Investigator (PI) will store these digital media files indefinitely on their password-protected computer, and no other study team members will have access.

The Principal Investigator will keep records of your participation in the study. Your research information and results must be kept for three (3) years after the completion of the study.

To protect confidentiality of your data, your study related records such as questionnaires and data files will be labeled or "coded" with an assigned subject number that will not include your name or identifying information. The Principal Investigator will maintain a linking document that will be able to trace your data back to you, which will be kept in a locked file cabinet and will be destroyed following verification and validation of the data, making the data de-identified. Once the link is no longer needed by the PI, it will be destroyed. The link will be maintained no later than the closure of the study. Electronic versions of any linking document(s) will be made and kept on a password protected computer. The computer version will be kept separate from your data, will be password-protected with access limited to the research team, and destroyed as noted above. Without the linking document(s), no one will be able to identify that the data came from you. Paper with any of your contact information related to this study will be shredded no later than the completion of this study.

We are also asking you if you agree to future use of your data for other research efforts and/or sharing with other researchers. If you agree to future use, your data will be kept indefinitely in digital format. You must agree to your data being maintained in a hard drive and database repository to participate in the study. Any documents that link your identity to your data will not be shared with other researchers.

We plan to tell others about our findings. When results of the research are published or discussed, no information will be included that would reveal your identity to others. In the event that media of you (e.g. photographs, video recordings - with or without sound) are shared for educational, reporting, or illustration purposes, your identity will be protected or disguised, such as by blocking or blurring your face and identifying marks (e.g. nametapes, tattoos, etc.) or framing the media from behind you.

Although the Principal Investigator will take steps to protect your confidentiality, there is a risk that your confidentiality may be broken in the form of an accidental release of information linking your name to your research records, or makes your participation known. The chances of this happening are small.

Although the Principal Investigator will take steps to protect your privacy, other people might see your personal or private attitudes, performance, or identifying information, or might learn that you helped Tufts University or the DEVCOM SC in their research efforts.

The research information that we will gather from you and/or your group is valuable. The research team would like to be able to store and use these data in the future for other studies concerning CES technology and to share the data with other scientists as they conduct their own work on CES technology to benefit the military and to share the data with the research community, journals in which study results are published, and with databases and data repositories used for research – as applicable. Prior to sharing the data with other scientists, we will destroy all documents that link your identity to your data. As we do not know the exact types of studies that will be done in the future, we are requesting your permission to use the information (data) that was collected as part of this study.

Research information that will be maintained WILL include:

a) Answers to questionnaires (e.g., demographics, emotional questionnaires, etc.)
b) Task performance and outcome data (e.g. eye movements, responses, etc.)
c) Photographs and videos (optionally)

The researchers will protect the confidentiality of your data by only sharing de-identified information. De-identified means we will destroy all documents (paper and/or digital) that link your identity to your data prior to sharing it with other researchers.

What are the risks or discomforts associated with this research? This study involves a non-invasive form of nervous system stimulation, called Cranial Electrotherapy Stimulation (CES). It also involves inducing stress with the threat and delivery of electric shock to the torso. There are two (2) risks you should be aware of when using these technologies.

1. There is a risk of developing side effects when receiving CES. These include temporary dizziness, vertigo, headache, nausea, lightheadedness, and/or skin irritation under the electrodes. Though most people do not experience these side effects, if you experience them, you may pause or stop participation at any time.
2. There is a risk of developing skin irritation when receiving torso shocks. These include temporary redness, rash, itching, and/or peeling. This skin irritation may last a few days after your participation and is expected to resolve without treatment. If you experience any of these side effects, you may pause or stop participation at any time.
3. There is a risk of developing psychological distress from handling the simulation rifle and shooting enemy targets. While this experience is similar to a first-person shooter video game, there is the risk that the task will make you feel sad, remorseful, fearful, or anxious. If you experience any of these emotions, you may pause or stop participation at any time. We will also encourage you to speak with a qualified mental health professional through the Tufts University Health Services (if you are affiliated with the university), or through private mechanisms.

What happens if I am injured in this study? If you need emergency medical care, Emergency Medical Service personnel will transport you to the nearest local hospital. Emergency Medical Care will be provided by calling 911, consistent with the Tufts University emergency response. It cannot be determined in advance which hospital or clinic will provide care. You and/or your insurance will be responsible for medical expenses.

How might I benefit from this research? There are no direct benefits to you aside from the educational experience of participating in the study. However, we expect that the results of this study will add to the body of knowledge on interactions between brain stimulation and cognitive performance.

What is the compensation for the research? You will receive $20USD per hour to take part in this study. You will not be reimbursed for any personal transportation.

What will happen if I choose not to participate? Your participation in this research is voluntary. You may refuse to participate in this study without any penalty or loss of benefits to which you are entitled. Deciding not to participate does not harm, or in any way affect, your future relationships with Tufts University, the DEVCOM Soldier Center, the Center for Applied Brain and Cognitive Sciences, or the U.S. Army.

Is my participation voluntary, and can I withdraw? Taking part in this study is your decision. Your participation in this study is voluntary. You are free to withdraw from the study at any point in time. Deciding to withdraw from the study does not harm, or in any way affect, your future relationships with Tufts University, the DEVCOM Soldier Center, the Center for Applied Brain and Cognitive Sciences, or the U.S. Army. If you would like to withdraw from the study at any point, please inform the Principal Investigator or a research team member.

Can I be removed from the research without my OK? Yes, you might be removed from participating in this research if:

- You cannot tolerate the minimum CES intensity for the study (250μA)
- You are unable to perform the tasks to a minimum level of accuracy.
- You cannot tolerate the torso shock belt for two successive sessions.
- You arrive for a CES session while ill or feeling high vestibular, anxiety, or pain symptoms.
- You cannot tolerate the CES for two successive sessions.
- If the study team determines that your continued participation is in any way detrimental to you or the study team.

Who do I talk to if I have questions? If you have questions, concerns, or have experienced a research-related injury, contact the research team at:

Kano Okano, Ph.D.
Phone: 617-627-1059

Email: kana.okano@tufts.edu

An Institutional Review Board ("IRB") is overseeing this research. An IRB is a group of people who perform independent review of research studies to ensure the rights and welfare of participants are protected. If you have questions about your rights or wish to speak with someone other than the research team, you may contact:

Tufts Social, Behavioral, and Educational Research IRB
75 Kneeland Street, Suite 623
Boston, MA 02111
617.627.8804
SBER@tufts.edu

Am I eligible to participate in this study? To determine if you are eligible to participate, please answer each of the following questions by circling YES or NO.

You might be eligible for this study if you answer YES to the following statements:

- You are 18-40 years of age, or 17 years if an emancipated minor **YES/NO**
- You can sit and stand freely. **YES/NO**
- You have never used CES in the past. **YES/NO**
- You agree to have your data stored in a repository for future use. **YES/NO**

You cannot participate in this study if you answer YES to any of the following questions:

- You are using prescription medications (other than oral contraceptives). **YES/NO**
- Women only:
    - You are pregnant or plan to become pregnant. **YES/NO**
    - You are nursing. **YES/NO**
- You have been diagnosed with a neurological or psychological disorder. **YES/NO**
- You have been diagnosed with cardiac disease. **YES/NO**
- You have been diagnosed with hypertension. **YES/NO**
- You have been diagnosed with insomnia (inability to sleep). **YES/NO**
- You have been diagnosed with a head injury (neurosurgery, concussion, fracture, hematoma, TBI). **YES/NO**
- You have been diagnosed with an illness that caused brain injury. **YES/NO**
- You have been diagnosed with any other brain condition. **YES/NO**
- You have metal in your head (shrapnel, surgical clips, etc). **YES/NO**

- You have an implanted medical device (pacemaker, insulin pump, etc). **YES/NO**

Is this study a clinical trial? Yes, a description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

STATEMENT OF CONSENT
I have read and considered the information presented in this form. I confirm that I understand the purpose of the research and the study procedures. I understand that I may ask questions at any time and can withdraw my participation without prejudice. I have read this consent form. My signature below indicates my willingness to participate in this study.

I consent to participate in this study.

_____	_____	_____
Name of Adult Participant	Signature of Adult Participant	Date

_____	_____	_____
Name of Research Team Member	Signature of Research Team Member	Date

This study optionally involves recording video and/or taking photographs of you. If collected, digital videos and/or photographs would be used for educational, reporting, or illustration purposes and will be stored indefinitely.

Do you agree to have video and/or audio recordings and photographs taken of you during this study? YES (initial)_____ NO (initial)_____

TUFTS UNIVERSITY
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title of the Study: Cranial Electrotherapy Stimulation (CES) Influences on Acute Stress Reponses
Principal Investigator: Kano Okano, Ph.D., Tufts University, Center for Applied Brain and Cognitive Sciences
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What is this study about?
Researchers at Tufts University are conducting a study on whether cranial electrotherapy stimulation (CES) can be used to reduce your body's stress response. You will be asked to participate in 22 visits to the laboratory. The first and last visits will assess your performance on a series of tasks while we monitor your hormones, heart and breathing rate, emotional stress, and cognitive performance. Between the first and last visits, you will participate in 20 sessions of CES, once per day over the course of 4-6 weeks. We are interested in whether CES changes your

stress responses and ability to perform tasks under stress. You are one of up to 100 participants to take part in this study. The study is supported by the U.S. Army DEVCOM Soldier Center (Natick, MA) who is sponsoring this research.

What will happen during this research?
If you agree to be in this research, your participation will include the following:

4. Visit the Center for Applied Brain and Cognitive Sciences (CABCS; Medford, MA) at Tufts University for a *baseline testing session* that will last about 3 hours. During this session, we will ask you to:
    a. Fill out questionnaires asking you about your demographics, emotions, and sensations.
    b. Complete a two-minute CES thresholding procedure. This involves placing ear clips onto your earlobes and slowly increasing the strength of the CES until you feel uncomfortable (such as feeling dizzy, lightheaded, vertigo, nausea). This procedure will make sure the strength of CES received during all sessions will be individualized and not uncomfortable. If you cannot tolerate a minimum intensity of CES, you will be dismissed from the study.
    c. Provide several saliva samples by placing a small piece of gauze under your tongue for 2 minutes.
    d. Learn and be tested on your memory for suspicious objects, a map, and your ability to distinguish enemies versus friendlies.
    e. Wear a chest strap that monitors heart rate and breathing, a pair of eye tracking glasses, and a waist strap that delivers uncomfortable and stressful electric shock.
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    g. Learn about the daily CES sessions (more information is below).
5. Visit the laboratory at CABCS **or** the DEVCOM Soldier Center laboratory for *20 CES sessions, one per day*. These sessions will be held during weekdays (M-F) and each session lasts about 40-60 minutes. During each session, we will ask you to:
    a. Complete a daily checklist and emotion questionnaire.
    b. Wear earlobe clips and electrodes that will provide you with either Active (real) or Sham (fake) stimulation from the CES device for 20 minutes. During this time, you will be asked to sit and relax.
    c. After stimulation is finished, we will ask you to complete an emotion questionnaire again, as well as a side effects checklist.

6. Visit the Center for Applied Brain and Cognitive Sciences (Medford, MA) at Tufts University for a *follow-up testing session* that will last about 3 hours. During this session, your experience will be the same as in the *baseline testing session* (detailed above).

During the 20 daily CES sessions, we will use either an Active or Sham CES device, depending upon which group you are randomly assigned to. You and the experimenters will not know whether you are receiving active or sham CES.

The Active CES device used in this study (the Alpha Stim) is cleared by the U.S. Food and Drug Administration (FDA) for the treatment of anxiety, insomnia, and depression. Because our study is using the device with healthy participants, the device is being used in a manner that is for *investigational use only*. This means that the device is being used in a study examining its safety or effectiveness, and not for the treatment, diagnosis, or prevention of any disorder.

What will you do to protect my privacy? The researchers will make every effort to prevent anyone who is not on the research team from knowing that you provided information, or what the information is. Responses will not include names and will be presented to others only when de-identified and included with other responses.

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In order to maintain confidentiality and to avoid loss of privacy, we will assign unique codes to your data that will not contain any personally identifiable information. Only the Principal Investigator (PI) will have access to a master list and a key that matches you to the coded data (all data collected from you, including questionnaire responses, and logged behavioral data). This key will be kept locked on a password-protected computer or server.

All study data that we collect from you will be locked up or kept on password-protected

computer files and servers. When the study is closed and we have analyzed and verified all of the data, the consent forms and any documents that link your identity to your data will be destroyed after three years. If any reports and talks are given about this research, we will not use your name or identify you in any way.

This study may optionally involve recording video and/or taking photographs of you performing tasks. If you agree to have these collected, digital videos and/or photographs would be used for educational, reporting, or illustration purposes and will be stored indefinitely. The Principal Investigator (PI) will store these digital media files indefinitely on their password-protected computer, and no other study team members will have access.

The Principal Investigator will keep records of your participation in the study. Your research information and results must be kept for three (3) years after the completion of the study.

To protect confidentiality of your data, your study related records such as questionnaires and data files will be labeled or "coded" with an assigned subject number that will not include your name or identifying information. The Principal Investigator will maintain a linking document that will be able to trace your data back to you, which will be kept in a locked file cabinet and will be destroyed following verification and validation of the data, making the data de-identified. Once the link is no longer needed by the PI, it will be destroyed. The link will be maintained no later than the closure of the study. Electronic versions of any linking document(s) will be made and kept on a password protected computer. The computer version will be kept separate from your data, will be password-protected with access limited to the research team, and destroyed as noted above. Without the linking document(s), no one will be able to identify that the data came from you. Paper with any of your contact information related to this study will be shredded no later than the completion of this study.

We are also asking you if you agree to future use of your data for other research efforts and/or sharing with other researchers. If you agree to future use, your data will be kept indefinitely in digital format. You must agree to your data being maintained in a hard drive and database repository to participate in the study. Any documents that link your identity to your data will not be shared with other researchers.

We plan to tell others about our findings. When results of the research are published or discussed, no information will be included that would reveal your identity to others. In the event that media of you (e.g. photographs, video recordings - with or without sound) are shared for educational, reporting, or illustration purposes, your identity will be protected or disguised, such as by blocking or blurring your face and identifying marks (e.g. nametapes, tattoos, etc.) or framing the media from behind you.

Although the Principal Investigator will take steps to protect your confidentiality, there is a risk that your confidentiality may be broken in the form of an accidental release of information linking your name to your research records, or makes your participation known. The chances of this happening are small.

Although the Principal Investigator will take steps to protect your privacy, other people might see your personal or private attitudes, performance, or identifying information, or might learn that you helped Tufts University or the DEVCOM SC in their research efforts.

The research information that we will gather from you and/or your group is valuable. The research team would like to be able to store and use these data in the future for other studies concerning CES technology and to share the data with other scientists as they conduct their own work on CES technology to benefit the military and to share the data with the research community, journals in which study results are published, and with databases and data repositories used for research – as applicable. Prior to sharing the data with other scientists, we will destroy all documents that link your identity to your data. As we do not know the exact types of studies that will be done in the future, we are requesting your permission to use the information (data) that was collected as part of this study.

Research information that will be maintained WILL include:

a) Answers to questionnaires (e.g., demographics, emotional questionnaires, etc.)
b) Task performance and outcome data (e.g. eye movements, responses, etc.)
c) Photographs and videos (optionally)

The researchers will protect the confidentiality of your data by only sharing de-identified information. De-identified means we will destroy all documents (paper and/or digital) that link your identity to your data prior to sharing it with other researchers.

What are the risks or discomforts associated with this research? This study involves a non-invasive form of nervous system stimulation, called Cranial Electrotherapy Stimulation (CES). It also involves inducing stress with the threat and delivery of electric shock to the torso. There are two (2) risks you should be aware of when using these technologies.

4. There is a risk of developing side effects when receiving CES. These include temporary dizziness, vertigo, headache, nausea, lightheadedness, and/or skin irritation under the electrodes. Though most people do not experience these side effects, if you experience them, you may pause or stop participation at any time.
5. There is a risk of developing skin irritation when receiving torso shocks. These include temporary redness, rash, itching, and/or peeling. This skin irritation may last a few days after your participation and is expected to resolve without treatment. If you experience any of these side effects, you may pause or stop participation at any time.
6. There is a risk of developing psychological distress from handling the simulation rifle and shooting enemy targets. While this experience is similar to a first-person shooter video game, there is the risk that the task will make you feel sad, remorseful, fearful, or anxious. If you experience any of these emotions, you may pause or stop participation at any time. We will also encourage you to speak with a qualified mental health professional through the Office of Medical Support and Oversight (OMSO).

What happens if I am injured in this study? If you need emergency medical care, Emergency Medical Service personnel will transport you to the nearest local hospital.

If you are injured because of your participation in this research and YOU ARE A DOD healthcare beneficiary (e.g., active duty in the military, military spouse or dependent), you are entitled to medical care for your injury within the DOD healthcare system as long as you remain a DOD healthcare beneficiary. Emergency Medical Care will be provided by calling 911, consistent with the DEVCOM SC emergency response. This care includes but is not limited to free medical care at Army hospitals or clinics.

Emergency Medical Care will be provided by calling 911, consistent with the DEVCOM SC emergency response. It cannot be determined in advance which hospital or clinic will provide care. You and/or your insurance will be responsible for medical expenses.

Transportation to and from Army hospitals or clinics will not be provided. No reimbursement is planned if you incur medical expenses to treat research-related injuries. No compensation is planned 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 OR the DEVCOM SC Human Protections Director (HPD) (508)-206 3720.

How might I benefit from this research? There are no direct benefits to you aside from the educational experience of participating in the study. However, we expect that the results of this study will add to the body of knowledge on interactions between brain stimulation and cognitive performance.

What is the compensation for the research? You will not be paid to take part in this study. Transportation to the Tufts University campus will be arranged at no cost to you, and you will not be reimbursed for any personal transportation.

What will happen if I choose not to participate? Your participation in this research is voluntary. You may refuse to participate in this study without any penalty or loss of benefits to which you are entitled. Deciding not to participate does not harm, or in any way affect, your future relationships with Tufts University, the DEVCOM Soldier Center, the Center for Applied Brain and Cognitive Sciences, or the U.S. Army.

Is my participation voluntary, and can I withdraw? Taking part in this study is your decision. Your participation in this study is voluntary. You are free to withdraw from the study at any point in time. Deciding to withdraw from the study does not harm, or in any way affect, your future relationships with Tufts University, the DEVCOM Soldier Center, the Center for Applied Brain and Cognitive Sciences, or the U.S. Army. If you would like to withdraw from the study at any point, please inform the Principal Investigator or a research team member.

Can I be removed from the research without my OK? Yes, you might be removed from participating in this research if:

- You cannot tolerate the minimum CES intensity for the study (250μA)
- You are unable to perform the tasks to a minimum level of accuracy.
- You cannot tolerate the torso shock belt for two successive sessions.
- You arrive for a CES session while ill or feeling high vestibular, anxiety, or pain symptoms.
- You cannot tolerate the CES for two successive sessions.
- If the study team determines that your continued participation is in any way detrimental to you or the study team.

Who do I talk to if I have questions? If you have questions, concerns, or have experienced a research-related injury, contact the research team at:

Kano Okano, Ph.D.
Phone: 617-627-1059
Email: kana.okano@tufts.edu

An Institutional Review Board ("IRB") is overseeing this research. An IRB is a group of people who perform independent review of research studies to ensure the rights and welfare of participants are protected. If you have questions about your rights or wish to speak with someone other than the research team, you may contact:

Tufts Social, Behavioral, and Educational Research IRB
75 Kneeland Street, Suite 623
Boston, MA 02111
617.627.8804
SBER@tufts.edu

Am I eligible to participate in this study? To determine if you are eligible to participate, please answer each of the following questions by circling YES or NO.

You might be eligible for this study if you answer YES to the following statements:

- You are 18-40 years of age, or 17 years if an emancipated minor **YES/NO**
- You can sit and stand freely. **YES/NO**
- You have never used CES in the past. **YES/NO**
- You agree to have your data stored in a repository for future use. **YES/NO**

You cannot participate in this study if you answer YES to any of the following questions:

- You are using prescription medications (other than oral contraceptives). **YES/NO**
- Women only:
    - You are pregnant or plan to become pregnant. **YES/NO**
    - You are nursing. **YES/NO**

- You have been diagnosed with a neurological or psychological disorder. **YES/NO**
- You have been diagnosed with cardiac disease. **YES/NO**
- You have been diagnosed with hypertension. **YES/NO**
- You have been diagnosed with insomnia (inability to sleep). **YES/NO**
- You have been diagnosed with a head injury (neurosurgery, concussion, fracture, hematoma, TBI). **YES/NO**
- You have been diagnosed with an illness that caused brain injury. **YES/NO**
- You have been diagnosed with any other brain condition. **YES/NO**
- You have metal in your head (shrapnel, surgical clips, etc). **YES/NO**
- You have an implanted medical device (pacemaker, insulin pump, etc). **YES/NO**

Is this study a clinical trial? Yes, a description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

STATEMENT OF CONSENT
I have read and considered the information presented in this form. I confirm that I understand the purpose of the research and the study procedures. I understand that I may ask questions at any time and can withdraw my participation without prejudice. I have read this consent form. My signature below indicates my willingness to participate in this study.

I consent to participate in this study.

_____	_____	_____
Name of Adult Participant	Signature of Adult Participant	Date

_____	_____	_____
Name of Research Team Member	Signature of Research Team Member	Date

This study optionally involves recording video and/or taking photographs of you. If collected, digital videos and/or photographs would be used for educational, reporting, or illustration purposes and will be stored indefinitely.

Do you agree to have video and/or audio recordings and photographs taken of you during this study? YES (initial)_____ NO (initial)_____