

Uniformed Services University of the Health Sciences

Consent for Voluntary Participation in a Research Study

1. PARTICIPANT NAME _____.

2. TITLE OF RESEARCH: Brain Synchronization and Neuropsychological Tests for Traumatic Brain Injury.

3. INVESTIGATORS' NAMES: Paul E. Rapp, Principal Investigator; David Keyser, and Brenna Rosenberg, Associate Investigators

4. RESEARCH ENTITY

This research study is being done by researchers at the Uniformed Services University of the Health Sciences and is funded by the Department of Defense.

5. CONSENTING FOR THE RESEARCH STUDY

This is a long and an important document. If you sign it, you will be authorizing the Uniformed Services University to perform research studies on you. You should take your time and carefully read it. You can also take a copy of this consent form to discuss it with family members, physician, attorney or anyone else you would like, before you sign it. Do not sign it unless you are comfortable with participating in this study.

6. YOUR RIGHT TO PRIVACY AND CONFIDENTIALITY

Very specific information on your right to privacy and the confidentiality of the use and disclosure of your personal health information can be found at the end of this consent form. We need your authorization to collect information about your medical history before you participate in this study. To participate in this research study you must read and sign the authorization at the end of this consent form.

7. PURPOSE OF THE RESEARCH

You are being asked to participate in a research study. The purpose of this project is to find out what happens in your brain when you perform simple tasks. We are also looking to see if the brain responses are different in people with traumatic brain injury (TBI). First, you will be given a simple 4 question assessment to determine if you are in the control or TBI group. If you are in the control group you will be prepared for EEG data collection. If you are in the TBI group you will be given some additional assessment tools using the computer. This is a series of reaction time tests. You will see simple questions on a computer and respond by pressing a button. These tests are part of a NeuroCognitive Assessment Test.

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Participant's Initials ____ Date _____

We want to learn how results change from day to day. We want to see if these results change with some common interventions for TBI. You will be asked to visit the laboratory four times and each time will be the same routine. The visits will be scheduled at your convenience approximately 4 weeks later, 3 months later, and 6 months later. Each visit will take about two hours. Evening and weekend appointments may be available.

The “brain waves” measured from participants are small electrical signals that our brains produce all the time when we do different things, even when we sleep. These signals can be detected by placing electrodes at different places on your scalp. These electrodes are small metal discs that are temporarily held in place with the aid of a paste or as part of a cap that is worn on the head. The electrodes work like little antennas, picking up very small electrical currents that occur on your skin. These electrodes will not apply electricity to you, nor will they puncture, cut, pinch or perforate the skin. The procedure does not allow us to know what you’re thinking. It is not a threat to your personal privacy.

This small study will be conducted in this laboratory and at collaborating laboratories using personnel who are approved for this protocol and have been approved by the USUHS Institutional Review Board. About two hundred and fifty healthy individuals and two hundred and fifty individuals with TBI will be asked to participate in order to learn more about how the brain processes information and the impact of TBI on these processes.

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8. PROCEDURES TO BE FOLLOWED

Since TBI has been associated with symptoms such as anxiety, irritability, sleep disorders, etc. we will give each participant a packet of information detailing mental health resources available to you should you want help with any of these potential problems. Before you participate in the study, you will be asked four questions about your past history of head injury. If you have had an injury to your head we will administer a standard battery of tests in the form of questionnaires and computer tests. You will complete about half of these on your own and the investigator will ask you the remainder of the questions. These questionnaires will help us understand your injury. This normally takes about 2 hours but may require an additional visit. All of your answers are confidential.

If you are not comfortable answering any of the questions that are asked as part of the standard battery you can opt to not answer them. If any part of the standard battery makes you upset or distressed we can help in obtaining a referral for you to see a trained professional who can help you process these feelings. If you are a member of the armed services or a government employee that referral will be through your government insurance program. If you are a civilian and not a dependent of a service member or government employee we will make this referral through your private insurance. We will have someone to escort you to the proper office if you so choose.

During the experiment, you will be asked to remain seated for 30 to 40 minutes. We will provide a break before we start the data collection process. During that time you will be asked to look at the computer screen or a small box with lights on it where lines, words, and images are displayed, and sometimes listen to tones played on a pair of headphones that you will be wearing. The words

Participant’s Initials _____ Date _____

are common English words and the images are lines, shapes, simple patterns and common objects. None of the words or pictures is designed to be upsetting.

Data collection will take place in a private room using a portable EEG collection unit and administered by trained personnel who are part of this study.

From your point of view, this procedure is identical to any doctor's EEG test. First, we take measurements of your head to determine the exact placement of the electrodes. Then we place a cap with electrodes attached on your head. Then we will add some gel into the electrodes so that electrical contact can be made with your head. You will then be given simple instructions like "Keep your eyes closed and relax" for eight short EEG recording sessions. At the end of the experiment we will remove the cap with the electrodes and wash away the gel with the aid of some water.

Our electrode application procedures and recording methods are standard throughout the world. The experiment does not involve shaving your head or breaking your skin in any way.

After the recording has been taken, we will have a brief conversation. We will want to hear your impressions of the experiment. We will also want to address any questions that you might have.

9. NUMBER OF PEOPLE THAT WILL TAKE PART IN THIS STUDY

Up to 250 participants with TBI are expected to take part in this study. An additional 250 participants will take part as healthy controls.

10. AMOUNT OF TIME FOR YOU TO COMPLETE THE STUDY

You will be part of this study for about six months.

11. BENEFITS

This is a test to collect basic scientific information about brain waves and TBI. It does not benefit your personal health in any way.

12. POSSIBLE RISKS OR DISCOMFORTS/CONSTRAINTS

Participation in this experiment does not bring any foreseeable risk to your personal health or wellbeing. If you do become upset or distressed as a result of answering the questions that are part of our standard battery then we can help in obtaining a referral for you to see a trained professional who can help you process these feelings.

The only anticipated physical discomfort results from cleaning the small amount of gel from your hair once the session is over. This is done by gently applying warm water with a paper towel.

There is only one report published in the medical literature describing hair loss while recording EEG over the last 30 years, and this was limited to experiments where electrodes were held in place for several hours. We do not anticipate any hair loss with these procedures.

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You should be aware that there is also a very small risk of suffering skin irritation due to the substances present in the gel or the electrodes. Although these substances are not toxic, irritating or dangerous in any way to most people, it is possible that they may unexpectedly cause you some irritation.

You will not be identified as a participant in the study in any of the published papers that describe the study. All participants will be given a participant number and will be identified by that number in all internal data files. Additional issues concerning confidentiality are addressed in Section 13.

13. CONFIDENTIALITY/PRIVACY AND HOW YOUR IDENTITY AND YOUR RESEARCH RECORDS WILL BE MAINTAINED

All information you provide as part of this study will be confidential and will be protected to the fullest extent provided by law. Your responses to our questions will be maintained in a locked filing cabinet in the laboratory offices in the Department of Military and Emergency Medicine. Records related to this study will be accessible only to those persons directly involved in conducting this study, representatives of USAMRMC, and members of the USUHS Institutional Review Board (IRB), which provides for protection of human research volunteers. In addition, the IRB at USUHS and other federal agencies that help protect people who are involved in research studies, may need to see the information you give us. Other than those groups, records from this study will be kept private to the fullest extent of the law. Scientific reports that come out of this study will not use your name or identify you in any way.

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14. CONDITIONS WHICH YOUR PARTICIPATION IN THIS STUDY MAY BE STOPPED WITHOUT YOUR CONSENT

The investigator may stop you from taking part in this study in the very unlikely event that being in the study is unsafe or dangerous to you. The investigator may also stop you from participating if you experience difficulty in following the procedures.

15. IF YOU DECIDE TO STOP TAKING PART IN THIS STUDY AND THE INSTRUCTIONS FOR STOPPING EARLY

Participation in this study is voluntary, and you can refuse to be in the study or stop at any time without the loss of the care benefits to which you are entitled, if you should suffer an injury as a result of this study.

16. PERMISSION TO CONTACT YOU IN THE FUTURE

In the future we may want to ask you some additional questions about the experiment, or we may want to invite you to participate in future similar experiments. If you do not want us to contact you in the future check the box below and initial next to it.

_____ I do not want to be contacted in the future.
Initial

Participant's Initials _____ Date _____

17. COMPENSATION TO YOU IF YOU ARE INJURED AND LIMITS TO YOUR MEDICAL CARE

This study will not entail any physical or mental risk beyond those described above. We do not expect complications to occur, but if for any reason, you feel that continuing this study would constitute a hardship for you, we will end your participation in the study.

In the event of a medical emergency while participating in this study or medical treatment required as a result of your participation in this study, you may receive emergency treatment in the facility you are in or a nearby Department of Defense (military) medical facility (hospital or clinic). Treatment/care will be provided even if you are not eligible to receive such care. Care will be continued until the medical doctor treating you decides that you are out of immediate danger. If you are not entitled to care in a military facility, you may be transferred to a private civilian hospital. The attending doctor or member of the hospital staff will go over the transfer decision with you before it happens. The military will bill your health insurance for health care you receive which is not part of the study. You will not be personally billed and you WILL NOT be expected to pay for medical care at our hospitals. If you are required to pay a deductible you may make a claim for reimbursement through the Uniformed Services University Office of General Counsel.

In case you need additional care following discharge from the military hospital or clinic, a military health care professional will decide whether your need for care is directly related to being in the study. If your need for care is related to the study, the military may offer you limited health care at its medical facilities. This additional care is not automatic.

If at any time you believe you have suffered an injury or illness as a result of participating in this research project, you should contact the Office of Research at the Uniformed Services University of the Health Sciences, Bethesda, Maryland 20814-4799 at (301) 295-3303. This office can review the matter with you, can provide information about your rights as a participant, and may be able to identify resources available to you. If you believe the government or one of the government's employees (such as a military doctor) has injured you, a claim for damages (money) against the federal government (including the military) may be filed under the Federal Torts Claims Act. Information about judicial avenues of compensation is available from the University's General Counsel at (301) 295-3028.

18. CONTACT FOR QUESTIONS OR PROBLEMS

If you have any questions about this research, you should contact Paul E. Rapp, Ph.D., the person in charge of the study. His telephone number at USUHS is 310-295-3590. Even in the evening or on weekends, you can leave a message at that number. If you have questions about your rights as a research participant, you should call the Director of Human Research Protections at USUHS at 310-295-9534. He is your representative and has no connection to the researchers conducting this study.

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SIGNATURE OF RESEARCH PARTICIPANT OR LEGAL REPRESENTATIVE

You have read (or someone has read to you) the information in this consent form. You have been given a chance to ask questions and all of your questions have been answered to your satisfaction.

Participant's Signature

Date

Participant's Printed Name

SIGNATURE OF INVESTIGATOR

You have explained the research to the participant, or his/her legal representative, and answered all of his/her questions. You believe that the volunteer participant understands the information described in this document and freely consents to participate.

Investigator's Signature

Date

(must be the same as the participant's)

Investigator's Printed Name

SIGNATURE OF WITNESS

Your signature as witness is intended to attest that the information in the consent document and any other information was explained to and apparently understood by the participant, or the participant's legal representative, that questions and concerns were addressed and that informed consent was freely given.

Witness' Signature

Date

(must be the same as the participant's)

Witness' Printed Name

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