Authorization for Research Use of Protected Health Information
Uniformed Services University of the Health Sciences

Protocol Title: Brain Synchronization and Neuropsychological Tests for Traumatic Brain Injury.

Principal Investigator: Paul E. Rapp, Ph.D., Department of Military and Emergency Medicine

Protocol #: F191DX-S2

Study Site: ___USUHS, ___Univ. VA, ___Camp Lejeune, ___Fort Bragg, ___Balt. VA, ___Dr Esty

The Federal Health Insurance Portability and Accountability Act (HIPAA) includes a Privacy Rule that gives special safeguards to Protected Health Information (PHI) that is identifiable, in other words, can be directly linked to you (for example, by your name, birth date, etc.). We are required to advise you how your PHI will be used.

1. What information will be collected?
For this research study, we will be collecting information about your general health and past events that may lead or may have led to brain injury. If you have been a part of any event that may lead or may have led to brain injury we will be collecting data about the event(s) and any symptoms that you may be experiencing. We will collect answers to standardized assessment forms and collect data from your performance on standardized cognitive assessment tests. Additionally, we will be collecting brain wave data similar to data from standard EEG collection that you may have had done by a physician.

2. Who may use my PHI within the Military Healthcare System?
The members of the research team will have access to your health information in order to find out if you qualify to participate in this study and in what group you will be assigned to (healthy control group or brain injury group). These data will be collected each visit by a member of our research team to monitor changes in your responses. Additionally, your PHI may be made available to representatives of USAMRMC and health oversight groups such as the USUHS Institutional Review Board and the Institutional Review Board Portsmouth Navy Hospital.

3. What persons outside of the Military Healthcare System who are under the HIPAA requirements will receive my PHI?
A collaborating investigator from Duke University, Dr A. Krystal, Neurologist, will have secure access to your EEG data for analysis. The study sponsors my request to audit the data from this research. If it is clear that you are experiencing significant thoughts of suicide then we will need to contact professional support personnel to help you maintain safety for yourself.

4. What is the purpose for using or disclosing my Protected Health Information (PHI)?
The members of the research team need to use your PHI in order to analyze the information to determine the best way to diagnose brain injury and to measure progress and recovery of function.

5. How long will the researchers keep my Protected Health Information?
The research team from USUHS will keep the research data for up to three years after the end of the study. The master code will be destroyed when all analysis has been completed. The resulting database will not be destroyed.

6. Can I review my own research information?

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11 July 2013
Expires: 10 July 2014

You can receive a copy of the results of this research study if you so choose by requesting a copy and providing contact information to the study coordinator.

7. Can I cancel this Authorization?
Yes. If you cancel this Authorization, you will no longer be included in the research study. However, the information that has already been collected will be kept by the research team to assure patient safety. If you want to cancel your Authorization, please contact the Principal Investigator in writing.

8. What will happen if I decide not to sign this Authorization?
If you decide not to sign this Authorization, you will not be able to participate in this research study. Refusal to sign this Authorization will not result in any loss of medical benefits to which you are otherwise entitled.

9. Can my Protected Health Information be disclosed to parties not included in this Authorization who are not under the HIPAA requirements?
There is a potential that your research information will be shared with another party not listed in this Authorization in order to meet legal or regulatory requirements. Examples of persons who may access your PHI include representatives of the Clinical Investigation Regulatory Office, the Food and Drug Administration, the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP), and the DHHS Office for Civil Rights. This disclosure is unlikely to occur, but in that case, your health information would no longer be protected by the HIPAA Privacy Rule.

10. Who should I contact if I have any complaints?
If you believe your privacy rights have been violated, you may file a written complaint with the Office of Research at Uniformed Services University of the Health Sciences, 4301 Jones Bridge Road, Bethesda, Maryland 20814, Phone: 301-295-3303.

By signing this document I authorize USUHS personnel to use and disclose my Protected Health Information (PHI) collected about me for research purposes as described above.

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Expires: 10 OCT 2014

Print Name: _____

Signature: _____ Date: _____

If you are a parent, court-appointed representative, or acting as power of attorney, indicate your authority to act for the participant: _____

A copy of this signed Authorization will be provided to you.