University of Texas at El Paso (UTEP) Institutional Review Board Informed Consent Form for Research Involving Human Subjects

Protocol Title: EEG Task Classification.

UTEP: Department of Electrical and Computer Engineering (ECE).

Investigators

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1 Introduction

You are being asked to take part voluntarily in the research project described below. Please take your time making a decision and feel free to discuss it with your friends and family. Before agreeing to take part in this research study, it is important that you read the consent form that describes the study. Please ask the study researcher or the study staff to explain any words or information that you do not clearly understand.

2 Why is this study being done?

You have been asked to take part in a research study of task classification by means of Electroencephalography. This will involve wearing a cap on your head that will collect the normal electrical activity of your brain. During this time we will stimulate your brain with a series of images and sounds. Approximately, 16 individuals will be enrolling in this study at UTEP. You are being asked to be in the study because you are an adult (over the age 18) and are mentally and physically qualified for this type of experiment. If you decide to enroll in this study, you will be asked to assist only one experimental session that will last about three hours.

3 What is involved in the study?

If you agree to take part in this study, the research team will: Contact you with a questionnaire to ensure that you are qualified. In the event that you have a condition that would preclude you from participating there is no need for you to tell us what it is, simply let us know that you will not be participating. In the case that there are no issues with the questionnaire, we will schedule a time for the experiment. Once you arrive we will ask that you sign the consent form and answer the questionnaire that you previously viewed in order to ensure that there are no issues that may cause you harm, or taint experimental results. We will then ask you if there is anything that you need to take care of before the experiment begins, such as using the restroom or making a phone call. This will be the last opportunity to do so for approximately one hour. First the circumference of your head should be determined using a tape measure. This measurement will establish your EEG electrode cap size. Then, a tape measure is used to measure the distance from the depression above your nose and below your forehead to the occipital protuberance (the natural bump in the back of the head). Next, the distance between the bottoms of each of your ear openings will be recorded. These measurements will give the necessary information for the correct placement of the EEG cap. This cap consists of 128 electrodes that will sense the normal electrical activity of your brain. The installation of the EEG cap will take no longer than 45 minutes. In order to properly catalog electrode positions for each test subject, the investigator will use the Patriot electrode localization system, and record the position of each of the 128 electrodes. Once this is complete we will start the experiment. The experiment may seem strange to you. There may be what seems to be random, meaningless images and sounds, but it is very important that you concentrate on them despite their seemingly random nature. Once the experiment is over we will remove the cap, and allow you to proceed to the designated facilities to clean the electrolytic gel from your scalp. Once you return we will again ask you to complete another questionnaire. This time the questionnaire will simply inquire as to your comfort level, and any improvements that you may suggest. After you have completed the questionnaire you will be free to leave at any time. In the following days, week, perhaps even years, the brain activity recorded will be used to develop classification techniques. These classification techniques are necessary to assist people with neurological disease, plus many other uses. For more information on the applications for this sort of research feel free to ask your test administrators.

4 What are the risks and discomforts of the study?

There are no known risks associated with this research.

5 What will happen if I am injured in this study?

The University of Texas at El Paso and its affiliates do not offer to pay for or cover the cost of medical treatment for research related illness or injury. No funds have been set aside to pay or reimburse you in the event of such injury or illness. You will not give up any of your legal rights by signing this consent form. You should report any such injury to Ricardo von Borries at (915-747-7959) and to the UTEP Institutional Review Board (IRB) at (915-747-8841) or irb.orsp@utep.edu.

6 What are the possible benefits of taking part in this study?

There will be no direct benefits to you for taking part in this study. This research may help us to develop classification techniques that will help people with neurological disease live a more normal life. There are also a countless number other potential applications for this sort of research such as the brain computer interface.

7 What other options are there?

You have the option not to take part in this study. There will be no penalties involved if you choose not to take part in this study.

8 Who is paying for this study?

Internal Funding:

Funding for this study is provided by UTEP Department of Electrical and Computer Engineering.

9 What are my costs?

There are no direct costs. You will be responsible for travel to and from the research site and any other incidental expenses.

10 Will I be paid to participate in this study?

You will not be paid for taking part in this research study.

11 What if I want to withdraw, or am asked to withdraw from this study?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you do not take part in the study, there will be no penalty. If you choose to take part, you have the right to stop at any time. However, we encourage you to talk to a member of the research group so that they know why you are leaving the study. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them. The researcher may decide to stop your participation without your permission, if he or she thinks that being in the study may cause you harm.

12 Who to call in case of any questions or concerns?

You may ask any questions you have now. If you have questions later, you may call the UTEP Electrical and Computer Engineering Department, or Ricardo von Borries directly at (915-747-7959). If you have questions or concerns about your participation as a research subject, please contact the UTEP Institutional Review Board (IRB) at (915-747-8841) or irb.orsp@utep.edu.

13 What about confidentiality?

1. Your part in this study is confidential. None of the information will identify you by name. All records will simply identify each test subject by sex, age, and any significant events that may or may not have affected the recorded data.

- 2. Every effort will be made to keep your information confidential. Your personal information may be disclosed if required by law. Organizations that may inspect and/or copy your research records for quality assurance and data analysis include, but are not necessarily limited to:
 - The sponsor or an agent for the sponsor.
 - Department of Health and Human Services.
 - UTEP Institutional Review Board

Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations.

All records will be maintained electronically.

14 Authorization Statement

I have read each page of this paper about the study (or it was read to me). I know that being in this study is voluntary and I choose to be in this study. I know I can stop being in this study without penalty. I will get a copy of this consent form now and can get information on results of the study later if I wish.

Name of Participant	Participant Signature	Date and Time
Consent form explained by	Signature	Date amd Time