

Information Sheet

1. **Study:** Studies with human subjects in the third-party funded M³S project (Modern Human-Machine Interface)

Duration of the Study: 15.05.2017 – 30.04.2020, linked to the duration of the M³S project supported by third-party funds (IT-1-2-001, Program EFRE NRW)

Study supervisor:

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2. **Invitation:**

Dear participant,

Thank you for your interest in our study. Before you decide to participate, it is important to understand why the study is being conducted and what exactly is being done. This document describes what happens if you decide to participate voluntarily. Please take your time to read this letter; we will be happy to answer any questions or provide you with information (by email: bci-lab@hsrw.eu).

3. **What are the risks for you?**

The risks of the study are minimal and are described below. Before participating, you will be introduced to the laboratory equipment and the course of study will be explained. EEG measurement is a very common method, which is regularly carried out both in the laboratory and in the hospital. As rapidly flickering images are viewed during the study, people with epilepsy are not allowed to participate in the study in order to avoid health risks.

There is an extremely unlikely possibility that flicker lights will cause seizures in people who are not yet known to have epilepsy.

To avoid the low risk of skin irritation caused by the electrode gel, subjects who are allergic to the gel ingredients (e.g. NaCl, Punicis, Tragacanth, Glycerin, etc.) should not participate.

- a. **Could your thoughts be read or recorded?** NO. No specific thoughts can be detected in the measured EEG activity. If we could, we would not use the indirect approach via the flashing lights.
- b. **Can the system transfer thoughts to my brain?** NO. In EEG measurements, only the naturally occurring brain activity is measured.

4. **Who conducts this study?**

This study is being conducted at the Rhine-Waal University of Applied Sciences under the supervision of Prof. Dr.-Ing. Ivan Volosyak, Professor of Biomedicine Engineering. Other employees and students of the Rhine-Waal University of Applied Sciences will also be involved in the study. This study was examined by the Ethics Commission of the Medical Faculty of the University of Duisburg-Essen.

5. What is the purpose of this study?

The aim of this study is to develop a system that allows people to exchange information only through brain activity. Such a system is called "Brain-Computer Interface (BCI)". It measures brain signals non-invasively in the form of an electroencephalogram (EEG) and derives computer commands from them. We want to further develop this system and make it available for various industrial sectors (e.g. games industry). To improve our research system, it is necessary to examine the EEG signals of several subjects.

6. Why is your participation helpful?

The main objective of this study is to develop a robust BCI system for controlling devices in everyday life. This requires several test series in our BCI laboratory with test persons.

7. Is it obligatory to participate?

Participation in this scientific study is completely voluntary. As a test subject, you have the right to cancel the test at any time without having to give any reasons. Before, during and after the experiment, the entire research team will support you.

- **What are the costs and/or disadvantages of participation?** Participation is free of charge. The test will take about 60 minutes and is safe and painless. We will apply electrode gel at a few (8-10) positions on your head. This electrically conductive electrode gel is water-soluble and can be easily washed out. The measurement is absolutely painless. Possibilities to wash the hair after the experiment, shampoo and hair dryer are available.
- **Will you get paid for the participation?** NO. We do not have the opportunity to pay for volunteers in this third-party funded project.
- **Is the recorded data managed with cautious?** The consent form is the only document with your name on it. All other data, EEG data, and questionnaires are pseudonymized (encrypted). The data will be pseudonymized immediately upon receipt by the head of the study, i.e. the respective person(s) will be given a number and the name will be consistently replaced by this number. Participant data (name, other information) are kept separate from the results. In the case of a publication, no names of the test persons are published. Photographs can be published, but only if you agree (see consent form). A refusal to take photographs does not in any way prevent your participation in the study.

8. How is participation conducted?

You will receive an EEG cap for the experiment. This usually contains up to 64 surface electrodes that measure brain activity. The data collected is processed by a computer.

Detailed procedure of the study:

- i. Please read this document (Information sheet) and the declaration of consent carefully and ask questions if necessary.
- ii. If you decided to participate, please sign the consent form and complete the first respondent questionnaire.
- iii. You will then be prepared for the EEG experiment; the EEG cap will be put on and the EEG gel will be applied.

- iv. After these preparations, you will work with the BCI system. You will look at some flickering boxes on the computer screen to perform some simple tasks using the measured brain activity (electroencephalogram, EEG):
- v. After recording the EEG signals, you will be asked to fill a second questionnaire.
- vi. After that, the cap will be taken off you. The remaining EEG gel can be wiped off with a paper towel. You can also wash and dry your hair afterward in our specially prepared washroom.

9. What happens if something goes wrong?

The potential risks of the participation are listed above. The university and the head of the study are liable for willful damage or damage caused by negligence. Please note that there is no accident insurance.

10. Is the data collected used to diagnose diseases?

NO. The collected data will only be used to evaluate the BCI study. They will not be transferred to a doctor.

11. What happens with the study results?

By signing the consent form you agree that your personal data will be collected and processed for the purpose of the above-mentioned study. Personal information includes, for example, your date of birth and gender, or other personal information collected during your participation in the study.

The personal data will be treated with strict confidentiality and will only be used for the purposes of managing and conducting the study as well as for research and statistical evaluation.

For any transfer of data to study participants, your data will be coded (pseudonymization of data). In pseudonymization, the name or other identification feature is replaced by a pseudonym (usually a multi-digit combination of letters or numbers, also called code) in order to exclude or significantly anonymize the identification of the person concerned.

With your consent, data and photos taken with your consent may be used for publication, for example in scientific journals. In case of publication, only anonymous data will be used. Please note that permission to take photos or videos is less likely to be recognized.

Your participation is voluntary and can be canceled at any time. You can revoke your consent to the use of your data at any time with future effect.

The personal data collected will be deleted at the end of the study. After that, a revocation is no longer possible.