*>Research institute<*

*>Research institute logo<*

*>Name of project leader<*

*>Full address of research institute<*

*>Name of project leader<*

Contact person for possible queries:

*>Name of investigator<*

Phone: *>Phone number of investigator<*

**General information for participants about the examination**

***>Research institute<***

Text in italics between angle brackets: please complete

Italicised text: Optional

**Study title: *>Title<***

Welcome to our study on “*>Title of study<*"! Thank you for your interest in this study.

The purpose of this study is to investigate whether >*etc.*<.

**The study**

This experiment is >*details about the duration and breaks<.* *In total, the experiment will last* >xx< hours.

Your task is to >*etc*.<.

>*Here you should describe what the test subjects will be asked to do during the experiment. Please address the participants directly, i.e. ‘You must...’*<.

>*Additional* *information, e.g. will they need to wear earplugs or headphones, instructions, intercom, rating scales, reaction boxes, etc.<.*

*>Information on the type of personal data collected<.*

**Data protection**

**Categories of personal data that is processed**

The following personal data is covered by data processing:

*For the sake of clarity, you can also delete the checkboxes at the top of the procedure description and only list which data is processed in the text field.*

**General categories of personal data:**

Categories may be, for example,

[ ]  contact details (name, address, email address, telephone numbers, etc.)

[ ]  demographic data (age, sex, etc.)

[ ]  bank account details (name, IBAN, bank, BIC, account balance, etc.)

[ ]  student data (attendance of classes, grades, etc.)

[ ]  billing data (name, address, identification number as creditor xx, date, amount paid, purpose of payment, bank account details if applicable.) Don’t forget, if Division 2 is involved

[ ]  …

[ ]  …

[ ]  …

**Special categories of personal data:**

[ ]  racial and ethnic background (...)

[ ]  political opinions (…)

[ ]  religious or ideological convictions or

trade union membership (...)

[ ]  genetic data (…)

[ ]  biometric data for the unique identification of a person (…)

[ ]  health-related data (…)

**Data processing method**

(…)

*What method is used? Code list, personal code word? Who has access to the “key” for assigning the pseudonyms? Where is the code list /code word stored?*

If you have any further questions, please contact the investigator.

*If the study involves an EEG, please use the following paragraph:*

*As part of this study, you will undergo an electroencephalogram (EEG). An EEG tracks and records brain wave patterns via electrodes which are either attached directly to your scalp with wires or integrated in an elastic cap.*

*There are no risks associated with an EEG. Since the brain’s potential fields are very weak at the scalp, to ensure a high-quality reading, the spots at which an electrode is attached are cleaned using a special paste and alcohol. Electrode gel is used to improve signal quality between the electrode and the scalp. The chemicals used have been clinically tested and can be easily washed off after the experiment. In rare cases, skin irritations may still occur. Occasionally, pressure points can be seen for a while at the spots where the electrodes or electrode cap was attached; in very rare cases, these spots remain visible for a few days after (e.g. redness). Please let us know if you suffer from any skin allergies or hypersensitivities.*

*If the study involves an fMRI, please use the following paragraph:*

*As part of this study, you will undergo a magnetic resonance imaging (MRI) test.*

*MRI scanning is a non-invasive procedure, i.e. it is not dangerous (according to current knowledge). In contrast to other diagnostic procedures, MRI scanning does not use ionizing radiation (radioactivity). Based on current knowledge and more than 20 years of experience with MRI technology, which is used daily in all major hospitals, there are no known side effects. Furthermore, there is no evidence of negative long-term effects of MRIs on the human body.*

*For the procedure, you will lie on a table which will then slide you into the opening of the cylinder-shaped MRI scanner. This is where the strong magnetic fields are located. A device (the magnetic coil) will also be placed around your head. When the images are being recorded you will hear a thumping sound. To avoid damage to your hearing, you will be given hearing protection before scanning starts. The examination will take around >xx< minutes. You will be asked to perform a simple task in the MRI scanner (duration approx. >yy< minutes). Afterwards, a more precise image of the structure of your brain will be recorded, which will take approximately >zz< minutes. It is therefore advisable to go to the toilet before the examination. Throughout the examination you will be able to talk to the examiners via an intercom system. You will also be given a panic button (pressure ball) in the scanner. If you wish, you can be removed from the MRI scanner at any time. Apart from possible discomfort resulting from lying still for a long time, you should not experience any pain during the examination.*

***Since MRI examinations require the use of magnetic fields, this excludes the participation of individuals who have electrical equipment (e.g. pacemakers, medication pumps, etc.) or metal parts (e.g. screws after bone fractures) in or on the body. Similarly, women of childbearing age who are or may be pregnant are also excluded from participation because the effect of the magnetic field on embryos has not been sufficiently studied. Since there is limited space inside the scanner itself, people with severe back problems or who are excessively overweight cannot be examined. You should also avoid making large, fast movements when in the scanner so as not to induce a magnetic current. [PLEASE ADD SCREENING SHEET]***

***Abnormal findings***

*The study is for research purposes only. A medical or psychological evaluation of your data will not take place. However, we may detect an abnormality in the results. In this case, we will inform you about it and recommend that you visit your GP to have the abnormality examined further. You may only participate in this study if you consent to being informed about any abnormal findings. If a disease is diagnosed during this diagnostic work-up, you may possibly suffer disadvantages as a result, e.g. it might be more difficult to get private health insurance or a life insurance policy.*

*If the study involves a TMS, please use the following paragraph:*

*As part of this study, you will undergo transcranial magnetic stimulation (TMS).*

*Thanks to TMS, we can find out how a region of the brain influences the processing of tasks. This procedure has also been used for routine diagnostics in neurology for more than 10 years. Magnetic fields are generated using an insulated electrical coil. These magnetic fields can stimulate nerve cells in the surface of the brain through the scalp and the skull. If the area of the brain responsible for movement is stimulated, the magnetic pulses result in slight movements, e.g. of the fingers.*

*Part 1 for online single- und triple pulse TMS This technique can be used not only to examine regions of the brain, but also to briefly disturb the function of those regions for a few seconds. The effect of TMS disappears completely within seconds. Short pulse sequences, consisting of up to three pulses in our examination, are administered within a few hundred milliseconds.*

*Part 2 for offline rTMS This technique can be used not only to examine regions of the brain, but also to briefly disturb the function of those regions, i.e. for a few minutes. This takes place in the form of a stimulation with TMS pulses lasting approx. 10 to 20 minutes. The actual experiment is performed separately from this phase, i.e. before or after stimulation with TMS.*

*A side effect of stimulation can be slight twitching of the forehead and head muscles during a TMS pulse, which can sometimes be unpleasant. On rare occasions, you may experience a dull feeling/pressure in the area of stimulation for one to two hours after stimulation. Magnetic stimulation causes no known permanent impairment or illnesses.*

*We always carry out our studies in line with the provisions stipulated in internationally used and recognised safety guidelines. Nevertheless, we cannot rule out with absolute certainty that, in exceptional cases, epileptic seizures may occur even in healthy test subjects and with the use of lower magnetic doses. The risk of such an incident is extremely low. If such a seizure does occur, there is a risk of injury (in particular a bitten tongue). Breathing may be obstructed by blood and saliva. You may lose control of your bladder and bowel. Such incidents have occurred mainly in people who previously had a seizure or brain damage. You may therefore only participate in this study if you have never had an epileptic seizure before.*

*All persons who perform TMS tests in our laboratory receive first-aid training on a regular basis. In the event of a seizure, a paramedic will be called and you will be taken to the nearest appropriate hospital.*

*In addition to epilepsy, there are some other health restrictions for participating in TMS studies. These are covered in the enclosed questionnaire, which the investigator will discuss with you once you have filled in the information.* ***[PLEASE ADD SCREENING SHEET]***

**Voluntary participation and anonymity**

Participation in the study is voluntary. You may withdraw from this study at any time without giving any reasons and without this resulting in negative consequences. Even if you withdraw from the study before the end, you are entitled to the *corresponding remuneration/credit hours for test persons* for the hours you participated in the study.

The data and personal notes collected as part of this study (described above) will be treated confidentially. As such, project staff members who have access to your personal data as a result of direct contact with you are bound by professional secrecy. Furthermore, the results of the study will be published anonymously, i.e. it will not be possible to identify you from the data.

**Data protection (Delete irrelevant passage. Please do not adapt any of the sentences if possible, as only the text here below has been agreed with the data protection officer)**

***Code list version:*** *The personal data mentioned above is collected and processed using a pseudonym at >institute details< i.e. a number and without stating your name. There is a code list (hard copy) which can be used to link your name to this number. This code list is only accessible to investigators and the project leader, i.e. only these persons can associate the collected data with your name. The code list is stored in a locked cabinet and once the >data has been collected/evaluated<, or by >enter date< at the latest, it will be destroyed. Your data will then be anonymous. As such, it will no longer be possible for anyone to associate the collected data with your name. The anonymous data will be kept for at least 10 years. As long as the code list has not been destroyed, you can request that all the data collected about you be deleted. Once the code list has been destroyed, however, we will no longer be able to identify your dataset. Therefore, we can only comply with your request to delete your data as long as the code list still exists.*

***“Personal code word” version:*** *The personal data mentioned above is collected completely anonymously, i.e. at no point will you be asked to give your name. Your answers and results will be recorded using a personal code word, which you create yourself based on a set of rules and that only you know. This means that no one can associate your data with your name. The anonymous data will be kept for at least 10 years. If you wish, however, you can request that all the data collected about you be deleted. For this, you will not have to tell us your name, just your code word. To create your code word, you will receive the document 'How to create your personal code word'. You keep this document. Please keep this document in a safe place as you will need it should you wish to delete your data at a later time.*

**Remuneration**

*For participating in the examination you will receive € xx per hour. This will be paid to you in cash/via bank transfer. If you receive the payment in cash, you must sign a receipt stating your name and address. If you receive the payment via bank transfer, you must provide your bank account details. You can also choose to receive ‘hourly credit for test persons’ ,which corresponds to the number of hours you participated in the study. This information is kept completely separate from the study data.*

*With different deletion periods:*

Your personal data will be stored for different amounts of time. Specifically:

e.g.

Billing data:

deleted 10 years after the end of the project. **Reason:** 10-year retention period of Division 2 acc. to Section 147 of the German Fiscal Code.

Demographic data:

made anonymous as soon as the purpose for data processing no longer applies, at the latest after 10 years (good academic practice).

Contact details:

deleted immediately after completion and evaluation of the data.

*If* ***publication of data*** *is intended, take this component*

**Duration of processing**

After evaluating all data and after completion of the study, but at the latest once the purpose of the research ceases to exist, your data will be made anonymous as quickly as possible – **in particular before publication for scientific purposes takes place** (e.g. specialist articles, conference papers, scientific databases [open data repositories]). The controller is obliged to do this in accordance with Section 13.2.1 of the Lower Saxony Data Protection Act (NDSG). Anonymisation means that nobody can identify you from the data. Your data is then no longer “personal” within the meaning of the legal provisions on data protection.

*If participants are remunerated and retention obligations exist:*

Your billing data will remain visible only to the accounting/billing system and its staff until it is deleted after ten years.

**Use of data**

This study is for research purposes only. (…)

**If no disclosure to third parties or third countries / international organisations**

Your personal data will not be disclosed to third parties without your consent.

**If disclosure to other persons/authorities/institutions/agencies:**

Your personal data can be disclosed to *>recipients/categories of recipients<* if *>state purpose of disclosure<.*

*If disclosure to third country or international organisation:*

Your personal data can be disclosed to *>third country or international organisation<*. There is / is not an adequacy decision for *>third country<*.

*Read more at: (https://datenschutz.hessen.de/datenschutz/internationales/angemessenheitsbeschl%C3%BCsse)*

*If there is not adequacy decision:*

When disclosing your personal data, the controller/processor shall provide appropriate safeguards within the meaning of Article 46 of the GDPR. A copy of these safeguards can be obtained from *>contact details point of contact<*.

*If personal data is to be further processed for* ***another purpose****:*

Your personal data can be further processed for the purpose of *>state purpose<.* *>Add further information about the new purpose<*

*Also add: Duration of storage, reference to abovementioned data subject rights, whether provision obligations exist; in relation to the further processing of personal data>.*

**Contact details of the controller and data protection officer**

|  |  |
| --- | --- |
| **Controller**Carl von Ossietzky University Oldenburg, a public corporation,represented by the PresidentAmmerländer Heerstr. 114-118 26129 Oldenburg Tel.: +49 441 7980 Fax: +49 441 7983000 Email: internet@uol.de Website: https://uol.de/en | **Data protection officer**University of OldenburgDer DatenschutzbeauftragteAmmerländer Heerstr. 114-118 26129 OldenburgTel.: + 49 441 7984196Email: dsuni@uol.deWebsite: https://uol.de/datenschutz/ |

<Further responsible within the framework of so-called “joint controllers”>

 *Note: only if there are joint controllers. Otherwise, delete the table below; in the case of processing, note within the item "Data processing procedure" that and who the processor is.*

|  |  |
| --- | --- |
| **Joint controller**Click or type here to enter text. | **Local data protection officer** Click or type here to enter text. |

**Contact person**

To contact us, in particular to exercise your data subject rights, please contact the project coordinator named in the letterhead.

*Note: Data subjects should first contact the project coordinators to exercise their data subject rights. If as project coordinator you have any questions on exercising data subject rights, please contact the DSM/ISM Unit at dsm@uol.de (for access requests) or the data protection officer dsuni@uol.de (all other data subject rights).*

**Legal basis**

The legal basis for collecting your personal data is, for example, consent according to Art. 6.1 (a) of the GDPR.

**Data subject rights**

* You have a **right of access** to your personal data (Art. 15 GDPR).
* You may without undue delay request the controller to **correct** any inaccurate personal data or to **complete** any incomplete personal data (Art. 16 GDPR).
* You have hereby been informed that you may request **erasure** of your personal data at any time (Art. 17 GDPR).
* You may request the **restriction of processing** if the legal requirements are met (Art. 18 GDPR).
* You have the right to receive your personal data **in a structured, common and machine-readable format** and to transfer this data to another controller (Art. 20 GDPR).
* You may **object** at any time to the processing of your personal data which is carried out on the basis of Article 6.1 (e) or (f) of the GDPR (Art. 21 GDPR).
* You have the right to **withdraw your consent at any time with future effect**, without affecting the lawfulness of processing based on consent before its withdrawal (Art. 7.3 GDPR) *If legal basis is consent.*

**Data subject rights (in short)**

* Right of access (Art. 15 GDPR)
* Right to rectification (Art. 16 GDPR)
* Right to erasure (Art. 17 GDPR)
* Restriction of processing (Art. 18 GDPR)
* Right to data portability (Art. 20 GDPR)
* Right to object to processing (Art. 21 GDPR)
* You can **withdraw** any consent you may have given at any timewith future effect, without affecting the lawfulness of processing based on consent before its withdrawal (Art. 7.3 GDPR) *If legal basis is consent.*

**Provision of data and consequences of non-provision**

The provision of your personal data is neither contractually nor legally required. You are not obliged to provide your personal data. Failure to provide your personal data results in *>state consequences of non-provision<.*

*or* The provision of personal data is required by law. *>State consequences of non-provision<.*

*or* The provision of personal data is contractually required. *>State consequences of non-provision<.*

*If automated decision-making in individual cases exists*

Automated decision-making in individual cases (incl. profiling) takes place as follows:

*(If automated decision-making in individual cases (incl. profiling) takes place, please contact the DSM/ISM unit at dsm@uol.de)*

**Right to lodge a complaint with a supervisory authority**

If you believe that the processing of your personal data violates data protection regulations, please contact the data protection officer of the controller (see above). Irrespective of this, you have the right to lodge a **complaint** with the competent supervisory authority. The competent supervisory authority is:

**The State Commissioner for Data Protection of Lower Saxony**Prinzenstraße 5
30159 Hanover

Tel.: +49 511 1204500

Fax: +49 511 1204599

Email: poststelle@lfd.niedersachsen.de

*>Research institute logo<*

*>Research institute with full address<*

*>Name of project leader<*

Contact person for possible queries:

*>Name of investigator<*

Phone: *>Phone number of investigator<*

**Declaration of consent**

*text in italics and between angle brackets*: please fill / mark

*paragraphs in italics:* optional

***>Research institute<***

**Study title: *>Title<***

I (name of participant in block capitals)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

have been informed about the study and test procedure *>in writing/verbally<*. I consent to >*broadly outline that to which the undersigned consents*<. Any questions I had about this study were answered completely and to my satisfaction by Mr/Ms \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

***Note to the project leader:*** *Use either the "Code list" or "Personal code word" version and delete the irrelevant section:*

***“Code list” version***

*I agree to the described collection and processing of data. >State here which data will be collected/processed. Specifically mention the type of data by name if health related.< This data is recorded and evaluated at >institute details< using a pseudonym, i.e. a number and without stating my name. There is a code list (hard copy) which can be used to link my name to this number. This code list is only accessible to the investigators and the project leader, i.e. only these persons can associate the collected data with my name. Once the >data has been collected/evaluated<, or by >enter date< at the latest, the code list will be destroyed. My data will then be anonymous. As such, it will no longer be possible for anyone to associate the collected data with my name. I am aware that I can revoke my consent to the storage or retention of this data without this resulting in negative consequences for me. I have been informed that I can request the deletion of all my data at any time. However, if the code list has already been destroyed, my dataset can no longer be identified and can therefore no longer be deleted. My data will then be anonymous. I agree that my anonymised data can be further used for research purposes and will be stored for at least 10 years.*

*Should any abnormalities be detected >in the EEG/in neuroimaging from the MRI examination/during the tests< that require treatment, I consent to this information being reported to me so that further examinations can be carried out if necessary. I have been informed that information about abnormal findings may have consequences under insurance law.*

***End of “Code list” version***

***“Personal code word” version***

*I agree to the described collection and processing of data. >State here which data will be collected/processed. Specifically mention the type of data by name if health related.< This data is recorded and evaluated at >institute details< anonymously, i.e. using a personal code word which I have created myself and which only I know. This means that no one can associate my data with my name. The sheet on which I created this code word is in my possession. I am aware that I can revoke my consent to the storage or retention of my data without this resulting in negative consequences for me. I have been informed that I can request the deletion of all my data at any time. I agree that my anonymised data can be further used for research purposes and will be stored for at least 10 years.*

*I have been informed that my name, address and telephone number are stated only on this declaration of consent. Should any abnormalities be detected during my examination >in the EEG/in neuroimaging from the MRI examination/during the tests< that require treatment, I consent to this information being reported to me so that further examinations can be carried out if necessary. I have been informed that information about abnormal findings may have consequences under insurance law.*

*Since all data is completely anonymous, I have been informed about the following procedure: If abnormalities are detected that require treatment, all relevant test participants will be contacted and asked to state whether the personal code word in question applies to them. I have been informed that if it is my own code word, I should contact the address provided and obtain further information. If it is not my code word, I can ignore the letter.*

***End of “Personal code word” version***

***Insert the following additional paragraphs only if relevant, otherwise delete.***

***ADDITIONAL PARAGRAPH FOR MRI DECLARATION OF CONSENT*** *I have been informed about the nature, meaning and scope of the planned MRI examination. I have read the information regarding the purpose of the examination as well as the participant information for MRI studies and agree to the examination. I have also been given detailed information orally. I do not have any metal parts or electrical devices in my body. My current physical condition does not prevent me from participating in the MRI examination. I have completed the questionnaire for participation in MRI studies truthfully. I have been made aware of the fact that no medical diagnostics will take place and that the images of the brain will not be used for medical diagnostics either. For women: I am not pregnant. Pregnancy can either be definitively ruled out or is not indicated after proper use of a pregnancy test.*

***ADDITIONAL PARAGRAPH FOR TMS DECLARATION OF CONSENT*** *I have been informed about the nature, meaning and scope of the planned TMS examination. I have read the information regarding the purpose of the examination as well as the participant information for TMS studies and agree to the examination. I have also been given detailed information orally. I have never had an epileptic seizure. I have completed the questionnaire for participation in TMS studies truthfully. For women: I am not pregnant. Pregnancy can either be definitively ruled out or is not indicated after proper use of a pregnancy test.*

***ADDITIONAL PARAGRAPH FOR DECLARATION OF CONSENT for image and sound recordings***

*I am aware that video/image/sound recordings will be made. The >video/image/sound recordings< are made and evaluated anonymously, i.e. using a personal code word which I have created myself and which only I know/using a pseudonym, i.e. a number and without stating my name in combination with a code list (hard copy) which can be used to link my name to this number. The code list is only accessible to the investigator and is destroyed once the data has been collected.< There is a very low probability that a person involved in the data evaluation process will recognise me. For this reason, all persons involved in the evaluation are bound by professional secrecy and may under no circumstances pass on confidential information to third parties.*

*I am aware that I can revoke my consent to the storage or retention of this data without this resulting in negative consequences for me. The >video/image/sound recording< will be stored in a locked cabinet. I have been informed that I can request the deletion of my recordings at any time, >as long as the code list (if there is one) has not been destroyed<. All recordings will be destroyed once the evaluation has been completed.*

*I consent to the described use of the collected recordings.*

*If the videos are to be used for demonstrations, please add the following paragraph. Otherwise, please delete.*

***Additional paragraph for demonstrations*** *I consent to my >video/image/sound recordings< being used for demonstration purposes at events with a limited number of participants (e.g. lectures). Please cross as appropriate O YES O NO.*

*I am completing this consent form for >video/image/sound recordings< voluntarily. I can revoke this consent at any time. If I object or withdraw my consent, I will not incur any expenses or be disadvantaged in any other way; I will >nevertheless/not< be able to participate in the study.*

I have had enough time to make a decision and am prepared to participate in the abovementioned study. I know that participation in the study is voluntary and that I can withdraw from the study at any time without stating reasons. In such case, I am aware that I am entitled to *>remuneration/hourly credit as a test subject<* for the hours I did participate in the study until that point.

I have received a copy of the information for participants regarding the examination and a copy of the declaration of consent. The information for participants forms part of this declaration of consent.

Place, date & signature of the participant: Name of the participant in block letters:

|  |  |  |
| --- | --- | --- |
|  |  |  |

Place, date & signature of the investigator: Name of the investigator in block letters:

|  |  |  |
| --- | --- | --- |
|  |  |  |