This folder contains important information if you consider participating in one of the studies at the Donders Centre for Cognition of the Donders Institute. Please read the following information carefully.

The Donders Institute is a university research centre investigating the brain, cognition and behaviour. The Donders Centre for Cognition (DCC) is part of the Donders Institute and has at its disposal various techniques in order to measure behaviour and brain activity. For our research we need volunteers to participate in various experiments, e.g. language, perception, action or memory tasks. All our research and research methods have negligible to minimal risks.

**Ethics check**
Each study you may participate in has been reviewed and approved by an independent ethics committee (the ‘Ethics Committee of Faculty of Social Sciences, Radboud University Nijmegen’, [https://www.radboudnet.nl/socialsciences/research/ethics-committee-social-science/](https://www.radboudnet.nl/socialsciences/research/ethics-committee-social-science/) or the medical ethics committee, [www.cmoregio-a-n.nl](http://www.cmoregio-a-n.nl)).

**Clinical data**
Researchers at the DCC do not examine the data from a clinical perspective. Participation in any of the experiments can therefore not be considered as a clinical or screening test. In exceptional circumstances the data collected may give indications concerning your health conditions. Prior to participation in these kinds of experiments you are required to provide name and address of your general practitioner. Additionally, in these types of experiments, we will archive your name, your personal identification number (of our subject database), and/or your (email) address. In case of a possible finding which is of clinical relevance you will be informed by a designated specialist of the DCC, or your general practitioner. In case you do not have a general practitioner (in the Netherlands), you will be informed by the Academic General Practitioner Center Heyendaal, for which you will then have to register as a patient once. Your insurance policy will cover these costs; In case you are uninsured the Academic GP Center is required to charge you a minimal amount for consultation. If you do not wish to be informed about findings concerning your health, you cannot participate in experiments at the DCC.

**Information about the experiment and giving consent**
You will receive a study specific information brochure from the researcher sufficiently in advance (this means minimally 24 hours in advance) of participation in the experiment. This will allow you time to reflect on your participation. Prior to participation, you are asked to sign a study specific informed consent form in which you confirm that you have been informed satisfactorily and are willing and able to participate voluntarily. The researcher will also sign the form, confirming that you have been informed about the experiment satisfactorily. The researcher will also ensure your privacy and that the necessary privacy conditions will be met. You have the right to withdraw from the experiment at any time without giving a reason. You can request disposal of your experimental data up to 1 month after participation in the study. After that your data will be pseudonymized, this means not
directly identifiable, and stored in a repository. An example of the study specific “informed consent” is attached to the applicable study specific information brochure.

Insurance
On legal grounds a liability insurance and in some cases an additional subject insurance has been concluded for subjects participating in studies at the DCC as part of the Donders Institute. The subject insurance covers damage due to participation in the study, becoming apparent during participation in the study or within four years after termination of participation in the study.

Use and preservation of your data
For our research it is necessary to collect, use and preserve personal information. This concerns personal data like name, address, date of birth, email address or personal identification number of the participant database. Use and preservation of your personal data is necessary for administrative and scientific goals. These goals are: the documentation of consent for participation in research, payment for participation, granting request to destroy data, to approach in the case of incidental findings, and to approach for future research (in case consent has been given for this). In some cases it is necessary to collect demographical data or data concerning your health, background, or preferences for scientific purposes. If you do not agree with this, you cannot participate in this research.

Confidentiality of your data
The information you provide for the purpose of the study will be handled carefully and will only be accessible to employees who are authorized to do so. Your data will be treated confidentially. All your research data will be coded in order to protect your privacy. Your name and other information, which might lead to your identity, will be kept separate from the experimental data. Only with a so called key file your experimental data can be linked to your identity. To protect your privacy this key file will also be stored apart from the research data. Only members of the research team who are directly involved and for whom it is necessary can access your personal data and the key file. Other parties involved in the research receive only access to the coded research data and won’t be able to identify you directly on the basis of this data. Reports or publications on the study will also only report your coded not directly identifiable research data.
In some studies additional audio, photo and/or video recordings will be obtained during the experiment. These are solely collected for scientific purposes. The experimenter will always inform you about this prior to participation, additionally asking for your approval. In all cases your privacy will be protected according to European law (European General Data Protection Regulation, GDPR)

Preservation time
Your data will be archived during for an established period of time, which is until 10 years after the research has been finalized. The connection between your personal data and your research data will be stored until maximally one month after finalization of the research.

Sharing your experimental data
Given the importance of verification, re-use and/or replication of research results, experimental data are shared or made public more often. Prior to this sharing the data will completely be pseudonymized (this means not traceable to your identity). In case of concerns regarding sharing your experimental data, you have the right to request disposal of your experimental data up to 1 month after participation. Some experimental data cannot be pseudonymized completely due to its nature, e.g. video-, photo or audio recordings. You have the right to disapprove sharing these data
with other researchers beyond the scope of the study. This can be done via the study specific consent form.

**Right to inspection**
Few other people or agencies have the right to inspect your data, both personal and research data. This is necessary in order to check if the research was properly and reliably conducted. The persons or agencies who can obtain access to your data for the purpose of verification are: a controller who works for the responsible institute, and national or international regulatory bodies such as the Ministry of Health. They will protect and keep your personal information secret. You are requested to approve this right to inspection. In case you do not agree, you cannot participate in the study.

**Future studies**
After participation in an experiment at the DCC, it may be the case that we would like to approach you again for a future study. You can indicate on the consent form whether you agree with this. In case you consent to be approached we will store name, address, email address and your identification number from the participant database, if applicable. Also in these future experiments, participation is always voluntary and consent will be sought every time you participate in a new experiment.

**Preparation of the experiment**
Generally, no extra preparation is required before participation. It is important that you are fit, alert and that you did not drink alcohol or used drugs the night before. Before the start of the actual experiment the researcher will explain the aims of the research and the applied measurement techniques to you. You will receive instructions about what you are asked to do during the experiment, such as watching a monitor, listen to sounds (possibly over a headset), perform a reaction task, make different movements or just lie still and relax. After everything has been fully explained, you will be asked to sign the consent form. Subsequent procedures depend on the research method that is being used. You can read more about this in the information brochures on EEG, moving chair, robot or EEG-FES.

**Payment**
Participation in experiments is reimbursed. The DCC gives this reimbursement by means of participant hours or ‘VVV giftcards (https://www.vvvcadeaubonnen.nl/). In this latter case we need your name and address for administrative reasons.

**Additional information, independent contact person and contact**
If you are unable to make it to the appointment (on time), please inform the responsible researcher as soon as possible. You may also contact this researcher for additional information or if you would like to withdraw from participating.

**After participation**
We appreciate hearing about your experiences as a participant. You can give your feedback – with or without personal information - via this webform. In case of questions or complaints about an experiment, contact the responsible experimenter first. You can also contact an independent contact person who is not involved in the study (independent contact person: Miriam Kos, of the Donders Centre for Cognition (dcclabcoordinator@socsci.ru.nl; tel 0243612650)) or fill out our webform. If applicable the independent contact person will contact you by phone.

**More information concerning your rights for processing data**
For more information with respect to compliance with your rights regarding the processing your personal data, you may contact the responsible entity for processing your data. The
Radboud University is responsible for compliance with the rights of processing personal data for this research. You may contact the office of the data Protection Officer of the Radboud University via privacy@ru.nl. More information about your rights regarding processing of personal data can be found at https://www.ru.nl/privacy/english/ and on the website of the Dutch Data Protection Authority: https://autoriteitpersoonsgegevens.nl/en.
General
Two techniques will be used during the experiment: EEG and FES. In this document you will find a comprehensive explanation of both techniques, along with a broad overview of the experiment and some suggestions on how to prepare for the experiment at home.

EEG recordings
Information processing in the central nervous system occurs, among other things, by electrical activity of the nerve cells. This continuous electrical activity of the brain, which is produced by the brain itself, can be measured and recorded by using electrodes. The result of such a measurement is called an ElectroEncephaloGram (or EEG, in short). In order to record the EEG, a cap (sort of bathing cap) will be put on your head. On this cap a large amount of measuring electrodes will be attached. Next to these electrodes, some electrodes will be placed around your eyes and behind your ears using small self-adhesive stickers. Your eyes, nose, mouth and the lower side of your face will remain free. To obtain good signals it is important that the resistance of the skin is not too high. The experimenter will reduce the resistance between your skin and the electrodes by using some alcohol and conducting gel.
Depending on the research goal, the duration of the EEG registration varies from about 30 minutes up to 2,5 hours. Some people experience the EEG recording as slightly uncomfortable. There are no medical risks to EEG recordings.

Functional Electrical Stimulation (FES)
In nerve cells, information is coded and transmitted as a series of electrical impulses, called action potentials. These action potentials represent a brief change in a cell’s electric potential, of about 80 to 90 micro Volt. The number of action potentials that occur in a unit of time is proportional to the intensity of the transmitted signal. These action potentials are the reason for a muscle to contract. Through external electrical stimulation, action potentials can be artificially created in a certain group of nerve cells, which results in a controlled muscle contraction. Functional electrical stimulation (in short: FES) is such a stimulation technique.
In this research we make use of the MOTIONSTIM 8 (see http://www.medel-hamburg.de). This FES device applies very weak electrical currents through external electrodes that are applied on the skin of the hand and/or arm. These currents cause a short and fast movement of the wrist, hand and/or fingers. The most effective placement of the electrodes will be carefully determined prior to the experiment. After this, the correct level of stimulation will be individually determined.

**Preparation at home**
To make the EEG-measurement-procedure run more smoothly, it is advised to run through the following steps:
- Wash and dry your hair beforehand
- Do not use gel, hairspray, etc.
- Do not use face cream or make-up
- If needed, bring a comb or hair brush
- Always bring (reading) glasses, also if you’re a contact lens user

**The experiment**
The researcher gives instructions about what you have to do during the experiment. It may be that you have to look at a computer screen, listen to sounds, carry out a reaction-time task, make certain movements, or just sit and be relaxed. The EEG experiment takes place in a separate room. During the measurement the door of this room is closed, but not locked. From the control room the researcher stays in contact with you over the course of the experiment by means of an intercom. The experimenter can see you by use of a camera. The measurement itself will not be noticeable to you. After the experiment the experimenter will remove the EEG cap, electrodes and FES electrodes. You can rinse out your hair, wash and dry it. For this purpose shampoo and towels are available. For hygienic reasons it is practical if you bring your own comb.

**Safety**
FES is tolerated well by participants. Some participants notice a light tingling sensation underneath the electrodes, which is easy to get used to. In very rare cases, the use of the external electrodes can cause irritation of the skin. This can be resolved by changing the stimulation settings or by using hypoallergenic electrodes. The risk associated with participation can be considered as negligible to minimal risk. No invasive procedures are involved.
You can NOT participate in a EEG-and-FES-experiment if one of the following applies
1) Head or brain surgery has been performed
2) You are using a pacemaker
3) You have cancer
4) You suffer from epilepsy
5) You suffer from a skin disease

If one of the above is applicable, please contact the researcher before the day of the experiment.
STUDY-SPECIFIC INFORMED CONSENT FORM

For participation in:*  [ ] Behavioural  [ ] EEG  [ ] Sled  [ ] Robot  [ ] EEG-FES

*tick the applicable box(es)

To be filled out by the PARTICIPANT prior to the start of the experiment:

I confirm that:
- I was satisfactorily informed about the study both verbally and in writing, by means of the general information brochure and additional study specific information brochure(s) (version 2.1, December 2018).
- I have had the opportunity to put forward questions regarding the study and that these questions have been answered satisfactorily.
- I have carefully considered my participation in the experiment.
- I participate voluntarily.

I agree that:
- My research data will be acquired and stored for scientific purposes as mentioned in the general information brochure until 10 years after the research has been finalized.
- Personal data is acquired for administrative and scientific purposes.
- The connection between my personal and research data is stored until maximally one month after finalization of this study.
- Demographic data or data concerning my health, background or preferences is collected for scientific purposes.
- My not directly identifiable experimental data will be made public for verification, re-use and/or replication.
- Regulatory authorities can access my data for verification purposes.
- I will be informed by a designated expert, my general practitioner or a general practitioner of the Academic General Practitioner Center Heyendaal about any information which is of clinical relevance to me.

I understand that:
- I have the right to withdraw from the experiment at any time without having to give a reason.
- I have the right to request disposal of my experimental data up to 1 month after participation.
- My privacy is protected according to applicable European law (European General Data Protection Regulation (GDPR)).
- My consent will be sought every time I participate in a new experiment.

I agree that I can be approached for a future study for comparable scientific research and to this end my contact details are stored until maximally one month after finalization of this study YES/NO (make a choice)

I give my consent to take part in this experiment:

Name:……………………………………………….. Date of birth:……………………………....... (dd/mm/yy)

Signature:.............................................................Date and place:……………………………………………....

To be filled out by the RESEARCHER prior to the start of the experiment:

The undersigned declares that the person named above has been informed both in writing and in person about the experiment. He /she guarantees subjects’ privacy protection according to Dutch law.

Name:……………………………………………….. PI group:……………………………………………….

DCC PPF number:…………………………………………………………………………………………………….

Signature:……………………………………………Date and place:…………………………………………….

December 2018, version 2.1
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<td>Have you had brain or head surgery?</td>
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<td>Do you suffer from epilepsy?</td>
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*If you answered Yes to one of the above questions, you cannot participate in the experiment.*

**Signature:**

**Date:**

**Name of general practitioner:**

**Address:**

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*This form is only to be used for research with people of 16 years or older, who are of sound mind and judgment. The person involved has to give his or her consent personally.*
**SCREENING FORM EEG research**  
*Version 2.1*

To be filled out **completely** by the **RESEARCHER** after the experiment

### Adverse event

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<td>• Relation to measurement procedure:</td>
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<td>• Action taken:</td>
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<td>• Abated/ follow up:</td>
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- **Follow Standard Operating Procedure Adverse Event**

### Incidental Finding

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- **Follow Standard Operating Procedure Incidental Finding**

**make a choice**