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/] or the medical ethics committee, [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. 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 (i.e. 24 hours) 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 anonymized 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.

Screening
When you register to participate in one of the studies at the DCC you'll have fill out a general questionnaire. General and demographic, as well as questions concerning your clinical history will have to be answered. This information is initially required in order to determine if you meet the inclusion criteria for participating in any of the research methods, or to decide whether you are a suitable candidate for a particular experiment. In some cases you may be excluded from an experiment based on specific exclusion-criteria. In addition to this general preparatory screening, the researcher will go through a screening form with you on the day of your participation in the study. During this screening you will only be asked to provide information that is strictly necessary to determine whether you are eligible to participate in the study.

Privacy
The information you provide during the screening and the study itself will be handled carefully and will only be accessible to the designated research team. Experimental data collected during the study are treated confidentially. The researcher stores all data under a subject code. In the records of the research only this code will be used. Only the members of the designated research team know the combination between you and the code. In some studies additional audio and/or video recording will be applied during the experiment. 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 Dutch law (Wet Bescherming Persoonsgegevens; WBP) and the future European general data protection regulation. This is all stated in writing in the privacy regulations of the DCC which is in line with the applicable Radboud University Privacy policy. If you are interested, you can request these regulations from the DCC lab coordinator, Miriam Kos, (dcclabcoordinator@socsci.ru.nl; tel 0243612650).

Right to inspection
Few other people have the right to inspect your anonymized experimental data in order to check for proper conduct. For instance: the research team concerned, an audit team, the ethics committee or the Inspection of the Ministry of Health.

Sharing your experimental data
Given the importance of checking and/or replicating the research results, experimental data are shared more and more for strictly scientific purposes with researchers or research consortia beyond the research team involved. Prior to this sharing the data will completely be anonymized (i.e. not traceable to your identity). In case of concerns of sharing your experimental data, you have the right to request disposal of your experimental data up to 1 month after participation. Your experimental data will be stored separately from your personal data in a database. Some experimental data cannot be anonymized 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.
Approach future studies
Participating in experiments at the DCC entails that you may be approached for participation in future studies. Also in these cases 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. Once 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 ‘iris checks’. In this latter case we need your address and BSN 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. 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](mailto:dcclabcoordinator@socsci.ru.nl); tel 0243612650) or fill out our webform. If applicable the independent contact person will contact you by phone.
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/of 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.

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.

**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.

**Additional information**
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 2.0, February 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 data will be acquired and stored for scientific purposes as mentioned in the general information brochure.
- My anonymized experimental data will be shared beyond the scope of this study for scientific purposes only with other researchers or research groups.
- 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/Dutch law.
- My consent will be sought every time I participate in a new experiment.

I agree that I can be approached for a future study.

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:……………………………………………....

February 2018, version 2.0
To be filled out by the PARTICIPANT prior to the start of the experiment

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>Are you younger than 16 years?</td>
<td></td>
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<tr>
<td>Have you had brain or head surgery?</td>
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<tr>
<td>Do you suffer from epilepsy?</td>
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</tbody>
</table>

If you answered Yes to one of the above questions, you cannot participate in the experiment.

Signature: ____________________  Date: ________________

Name of general practitioner: ____________________
Address: ____________________

* 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.
## Screen Form EEG Research
### Version 2.0

To be filled out completely by the RESEARCHER after the experiment

### Adverse event

**YES/NO**

If YES:

- Date and time of occurrence: ____________________ ______
- Description:

- Severity: mild/moderate-serious**
- Relation to measurement procedure: none/unlikely/possible/likely/definite**
- Action taken:

- Abated/ follow up:
  - Follow Standard Operating Procedure Adverse Event

### Incidental Finding

**YES/NO**

If YES:

- Date: ____________________ ______

- Follow Standard Operating Procedure Incidental Finding

**make a choice

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February 2018, version 2.0