DONDERS INSTITUTE

GENERAL INFORMATION
Version 2.2

This folder contains important information if you consider participating in one of the studies at the Donders Institute. Please read the following information carefully.
The Donders Institute is a university research centre investigating the brain. **The Donders Centre for Cognitive Neuroimaging** (DCCN) is part of the Donders Institute and has at its disposal several scanners using different techniques in order to measure brain activity, among which MRI scanners, several EEG devices, a NIRS-, a tCS- and a MEG device. For our research we need healthy adult volunteers (18 years and older) to participate in various experiments by means of investigating language, visual or auditory pathways. In some experiments additional stimuli will be applied in order to activate certain relevant brain areas, or register brain activity during sleep. In all cases you will be informed about these procedures in timely fashion prior to participation. All our research and all of the scanning methods are of negligible risk and minimal burden. No invasive procedures are involved.

Medical ethics Check

Before conducting research in healthy subjects, a study has to be reviewed and approved by an independent medical ethics committee (view: www.cmoregio-a-n.nl)
Above mentioned research conducted at the DCCN is covered by an overall protocol, approved by the 'Commissie Mensgebonden Onderzoek Regio Arnhem-Nijmegen' and registered under CMO number 2014/288.

Medical data

We want to emphasize that the researchers at the DCCN do not examine the data acquired from a medical perspective. Participation in any of the experiments cannot be considered as a medical nor screening test. In exceptional circumstances the new data collected may give indications concerning your health conditions. Prior to participation you are required to provide name and address of your home physician. In case of a suspected abnormality (incidental finding) which is of clinical relevance you will be informed by your home physician. In case you do not have a home physician (in the Netherlands) you are requested to register as a patient at the Academic General Practitioner Center Heijendaal. In the exceptional circumstance of a clinically relevant finding you will be either informed by your own home physician or the general practitioner of the Academic Center. 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.
You cannot participate in any research at the DCCN if you **do not** want be informed about an incidental finding.

Pregnancy

If you are pregnant or expect to be pregnant you can**not** participate in either of the studies.

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 the initiation of study-related procedures. This will allow you time to reflect on the potential benefits and risks and possible discomforts. Prior to participation the researcher will with you fill out a screening form in order to check if you are fit to participate in the study. Additionally, you are tied to sign a study specific informed consent form in which you confirm that you have been informed satisfactory and are willing and able to voluntarily participate. The researcher will also sign the form confirming that you have been informed about the experiment. The researcher will also ensure your privacy and the necessary privacy conditions will be met. You have the right to withdraw from the experiment at any time without having to give 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 a 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 all subjects participating in studies at the DCCN 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. (additional information in the supplement)

Use and preservation of your personal data and body.

Before and during study conduct it is necessary to collect, use and preserve personal information. This concerns personal data like name, address, date of birth etc. and some additional medical background information. Sometimes also body material (e.g. saliva) is collected. Use and preservation of these data are necessary to answer the scientific research question(s) and to publish results. We will ask your permission/ consent for this.
If you do not agree you cannot participate in this research.

Confidentiality of your data and body material.

All 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. This key file is kept by the researcher. Other researchers involved will only have access to your coded experimental data.

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 researcher knows the combination between you and the code. In some studies, additional audio and/or video recording will be applied during the experiment. This material will be only used for scientific purposes. Sometimes the measurements will take place during sleep in the evening or night. 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 the European General Data Protection Regulation. Results and publication of experimental data will always be coded.

Right to inspection

Few other people have the right to inspect your data. This concerns the coded as well as the uncoded data from which they may infer your identity. This is necessary in order to check if the research was properly and reliably performed. Persons or agencies who have access to check your data are: a controller working for the sponsor, national or international regulatory bodies, e.g. Inspectorate of the Ministry of Health. They will protect and keep your personal information secret. You are requested to approve/ consent for this right to inspection. In case you do not agree, you cannot participate in this study.

Preservation time on data and body material.

On location of the sponsor the data will be preserved for an established period of time, i.e. 10 years. The collected body material (saliva) will be destroyed immediately after data-analyses.

Sharing of your experimental data and approach future studies.

Experimental data are more and more shared for strict scientific purposes with other researchers or research consortia. This is important to check and/ or replicate the research results. Prior to sharing your experimental data, the data will be completely anonymized (i.e. not traceable to your identity). If you do not agree with this sharing policy, you cannot participate.
With respect to the informed consent procedure:

- ✓ Some experimental data cannot be anonymized due to their nature, e.g. video- or audio recordings). You have the right to disapprove sharing these data with other researchers beyond the scope of the study.

You are always asked whether you are willing to be approached for participation in future studies.

Preparation for the experiment

No extra preparation is required before participation. It is important that you are fit, alert and that you have not drank alcohol the night before. For MRI and MEG research it is important that you do not have any metal in/on your body during the experiment. You can read more about this in the information folders on MRI and MEG.

When you arrive please take a seat in the waiting room which is on the left side of the entrance hall. The researcher will come to pick you up and take you to the experiment room. He/she 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. For some experiments you will be additionally informed about the study specific procedures prior to participation. In all cases the experimenter will answer all your remaining questions concerning the experiment before participation. Once everything has been fully explained he/she will ask you to sign the consent form. Subsequent procedures depend on which technique is being used. You can read more about this in the information sheets on EEG, MEG, NIRS, tCS and MRI.

Payment

The payment for each experiment is:

From 18 years of age		Between 16-18 years of age	
Behavioural:	€ 8 per hour	Behavioral:	€ 4 per hour
EEG:	€ 8 per hour	EEG:	€ 4 per hour
MEG:	€ 8 per hour	MEG:	€ 4 per hour
fNIRS	€ 8 per hour	fNIRS:	€ 4 per hour
tCS	€ 8 per hour	tCS:	€ 4 per hour
fMRI:	€ 10 per hour	fMRI	€ 5 per hour

The DCCN will transfer the payment directly to your bank account within 6 weeks of your participation. For our administration we need your bank IBAN -account number, address and BSN (SOFI number).

Independent expert

When you have additional questions prior or during a study you may address these to an assigned independent expert. The independent expert is not involved in the study however capable of answering your questions.
Contact information of the assigned expert can be found in the study specific information brochure.

Additional information and contact

If you are unable to make it to the appointment (on time), please let us know as soon as possible. Telephone number: 024 – 36 10750. You may also call the number mentioned above for additional information or if you would like to withdraw from participation.
A special brochure has been developed by the Ministry of Health: " Medisch Wetenschappelijk onderzoek / general information for the subject" The brochure can downloaded from www.ccmo-online.nl. Hardcopies of the informationbrochure are available at the reception of the Donders Centre for Cognitive Neuroimaging.

After participation

It's possible to share your experience regarding your participation. Are you satisfied or perhaps not at all? Please let us know by means of a feedback-web form. You can find this form on the internet Participant Information site. http://www.ru.nl/donders/proefpersonen/proefpersonen-info/engelse-versie/participants/
We really appreciate your feedback!

More information concerning your rights for processing data.
For more information with respect to compliance of your rights processing your personal data, you may contact the responsible entity for processing your data: the Radboud University.

You may contact the data Protection Officer of the Radboud University : Ronald Sarelse. Tel. 024-3612340; mail r.sarelse@ru.nl. More information about your rights regarding processing of your personal data you can find on: https://autoriteitpersoonsgegevens.nl/en

Registration of the Research
This research is also registrered in the medical scientific research overview: the register of the CCMO in the Hague. This website does not consist of any information which might lead to your identity.

Annex to the Participants' information (March 2017)

The Donders Centre for Cognitive Neuroimaging has taken out insurance for the subjects in this scientific research. This insurance covers losses caused by death or injury resulting from participation in this scientific research, which reveals itself during the participation of the subject in the scientific research or within four years thereafter. The personal injury is deemed to have revealed itself at the time it is reported to the insurer.
In the event of a claim, you may contact the insurer directly.

The insurer is:
Onderlinge Waarborgmaatschappij Centramed B.A.
P.O. Box 7374
2701 AJ Zoetermeer, The Netherlands
Tel.: +31 70 3017070
Email: Schade@centramed.nl

The insurance provides a maximum cover of € 650,000 per subject and € 5,000,000 for the entire research, and € 7,500,000 per annum for all examinations of the same client.
The above amounts are included in the "Besluit verplichte verzekering bij medisch-wetenschappelijk onderzoek met mensen". Information on this "besluit" can be found at the website of the Central Committee Clinical Research involving Humans: www.ccmo.nl.

The insurance covers losses resulting from experiments. The insurance does **not** cover:
- Claims for injury that is inevitable or practically inevitable, given the nature of the experiment;
- Injury to the health which also would have occurred if you had not participated in the experiment;
- Injury caused by the subject's non- or partial adherence to the directions or instructions;
- Injury to the descendent(s), as a result of an adverse effect of the experiment on the subject or on the subject's descendent(s);
- Injury caused by an existing treatment method in an experiment into existing treatment methods;
- Injury resulting from the occurrence of a risk of which the subject was warned in the written information, unless the risk occurs in a more serious degree than was expected or said risk was highly unlikely to occur.

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Donders Centre for Cognitive Neuroimaging

SCREENING FORM BEHAVIOURAL
Version 2.2

To be filled out prior to the start of the experiment

Please answer the following questions first	Yes	No
- Do you suffer from claustrophobia?		
- Are you pregnant or do you think you are?		
- Are you younger than 16 years?		

If you have answered "Yes" to one of the above questions, you CANNOT participate in the experiment.

Subject name:

Date of birth:

** This form is applicable for research in healthy, competent adolescents/adults (≥16 year.) The subject involved needs to provide his or her written consent personally.*

P.T.O

SCREENING FORM BEHAVIOURAL
Version 2.2

To be filled out completely by the RESEARCHER after the experiment

Name: Project number:

Function: Sona systems study name:

Signature: Date:

☐ Payment …… euro

☐ No payment

Reporting Event or Finding:

Adverse Event **YES/ NO***

If YES: dd/mm/yyyy time

- Date and time of occurrence …….. …….
- Description:

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

o **Follow Standard Operating Procedure Adverse Event!**

Incidental Finding **YES/ NO***

If YES: dd/mm/yyyy

Date: ……..

- **Follow Standard Operating Procedure Incidental Finding!**

**make a choice*

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Donders Centre for Cognitive Neuroimaging

STUDYSPECIFIC INFORMED CONSENT FORM

For participation in: *

☐ **MEG** ☐ **EEG** ☐ **MRI** ☐ **NIRS** ☐ **tCS** ☐ **Behavioural**

***tick the appropriate box(es)**

I confirm that:

- I was satisfactorily informed about the study concerned both verbally and in writing by means of the general information brochure and additional study specific information brochure(s) (*CMO2014/288; May 2018, version(s) 2.2*).
- 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 of my own free will.

I agree that:

- My data/ body material will be collected and used for the purpose mentioned in the information brochure.
- I will be informed by my home physician or the academic GP of General Practitioner Center Heijendaal about any new information which is of medical relevance to me.
- For study purposes audio and/or video recordings may be made
- Beyond the scope of this study: my anonymized experimental data will be shared with other researchers or research groups

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 data will be protected according to applicable European privacy law.
- My consent will be sought every time I participate in a new experiment.
- For compliance check of the research few persons may have access to my (personal) data. These persons are mentioned in the information brochure. I consent for this.

I give my consent to take part in this experiment:

Name:……. Date of birth:……..... (dd-mm-yyyy)

Signature:..... Date and place:……..

I agree that for scientific purposes collected potential identifiable photo/video/audio recordings beyond the scope of this study will be shared with other researchers or research groups.

YES? NO/ not applicable*

I may be approached for a future neuroscientific study. **YES/ NO***

(*encircle choice)

To be filled 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.

Name:……. Project code:…….

SONA title of the study:…….

Signature:..... Date (dd-mm-yyyy):……..