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 apparatus, 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. 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 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 Heyendaal. 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 screeningform in order to check if you are fit to participate in the study. Additionally you are tied to sign a 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. An example of the 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)

Privacy

If you register to participate for one of the studies at the DCCN you'll have fill out a general questionnaire. Both general demographic as well as questions concerning your medical history are asked 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. This information is required to decide if you are a suitable candidate for a particular experiment. In some cases you may be excluded from an experiment based on the exclusion-criteria.
The list of questions contains only information that we require for our experiments. We guarantee all information will be handled carefully. We will not give personal data to any other than staff of the designated research-team. This is all stated in writing in the privacy regulations of the DCCN. If you are interested you can ask the secretary of the DCCN to show you the regulations, or ask for a copy to be sent by mail.
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. De 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).

Right to inspection

Few other people have the right to inspect your 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.

Consenting: sharing of your experimental data and future studies.

We would like to share your coded experimental data for strict scientific publication purposes with other researchers. If you do not agree to this we will respect your decision. You may note your decision on the study specific informed consent form prior to participation. 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 depends 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:

Behavioural:	€ 8 per hour
EEG:	€ 8 per hour
MEG:	€ 8 per hour
fNIRS	€ 8 per hour
tCS	€ 8 per hour
fMRI:	€ 10 per hour

The DCCN will transfer the payment directly to your bank account within 5 weeks of your participation. For our administration we need your bank IBAN -account number, address and BSN (SOFI number).

Independent physician

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

Mandatory Subject (WMO) Insurance policy

Please note this is a translation of an original Dutch document. The Dutch original and legally binding version of this document is available upon request

On legal grounds, the Stichting Katholieke Universiteit Nijmegen has concluded insurance for the participants in this study. This insurance covers damage due to death or injury resulting from participation in the study, becoming apparent during participation in the study or within four years after termination of participation in the study. The damage is deemed to have been revealed when it is reported to the insurer. Coverage for damage does not include damage as a result from the occurrence of a risk of which the participants has been informed about , unless the risk is expressed to the extent not foreseen or the risk is unlikely to occur.

The insurance coverage provides the following:
Maximum coverage of € 450.000,-- per subject and € 3.500.000 for the whole study and 5.000.000,-- for all research incurred by the organization per year. The coverage of specific damages and costs is also limited to certain amounts. This is included in the "Act compulsory insurance for medical research involving humans". Information can be found on the website of the Central Committee on Human Research: www.ccmo.nl

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In case of damage you can submit your claim to:
Onderlinge Waarborgmaatschappij Centramed B.A.
Postbus 191
2270 AD Voorburg
Email: Schade@centramed.nl

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INFORMATION ABOUT MRI

version 1.4

General

MRI stands for 'Magnetic Resonance Imaging'. This method allows us to take images of the inside of the human body. By using a strong magnetic field and radio waves radio signals are generated in the body. These signals are picked up by an antenna and with the help of a computer pictures of cross-sections of the human body can be produced. At the Donders Institute mainly a variation of this technique called fMRI (f = functional) is used. With fMRI it is possible to see both the structure and the activity of the brain. An fMRI experiment usually lasts one to two hours.

Preparation

Metal objects are attracted to the magnet and/or disturb the measurement. Also there is a slight chance metal can warm-up. Therefore please take into account the following:

- The clothing on your upper body may not contain any metal (e.g. zips, buttons, hooks, braces). This also applies to bras containing a metal brace wire.
- Jewellery, piercings, hairpins, glasses, etc with metal parts must be removed. Please do not use mascara as this sometimes contains metal fragments.
- Coins, keys, cigarette lighters, cell phones, penknives, cufflinks etc must be removed and can be stored in a locker. The same goes for bank cards, credit cards and chipcards. Otherwise the strong magnetic field will erase the information stored on the magnetic strip.

The experiment

After the researcher has informed you about the experiment you will enter the shielded magnet room and lie down on the movable table. Please relax and lie as comfortably as possible. During the experiment the scanner will make a lot of knocking sounds and noises of varying volumes. Ear protection is a must. Hence you will be given headphones or earplugs to reduce the noise. A frame (= the antenna) is placed over your head. It is important to lie as still as possible during the scanning. Hence your head is fixated with small cushions. Before the researcher moves you inside the scanner you will be given a rubber ball to hold in your hand. If you squeeze the ball during the experiment this will sound an alarm which tells the researcher to stop the experiment. During the scan the door to the MRI room is shut, but not locked.
An experiment consists of several scans. The shortest lasts for 10 seconds and the longest about forty minutes. In total a scan session lasts one to two hours. Via the intercom the researcher keep you informed about the progress of the experiment. not be locked. The researcher can see you via a video camera and you can communicate via an intercom. Sometimes the experiment will be video and/or -audio recorded for strict scientific purposes. The experimenter will inform you about this in timely fashion prior to the experiment.

Additional information

The risk associated with participation can be considered as negligible. No invasive procedures are involved.
You can **NOT** participate in a MRI-experiment if one of the following applies:

- Metal parts, that cannot be removed, are present in or on your upper body, e.g. plates, screws, aneurysm clips, metal splinters, piercings or medical plasters.
- Dental fillings, crowns, a metal wire behind the teeth, tattoos and contraceptive coils are allowed. The researcher will additionally inform you.
- Clothing on the upper body containing any metal e.g. zips, buttons, hooks, braces, metal yarn (LUREX). This also applies to bras containing a metal brace wire.
- You have an active implant, a pacemaker, insulin pump, neurostimulator and/or ossicle prosthesis.

If one of the below issues is applicable, please contact the researcher prior to the experiment

- You have a history of brain surgery.
- You suffer from epilepsy.
- You suffer from claustrophobia.
- You are pregnant or you think you are.
- You are younger than 18 years of age.

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SCREENING FORM MRI
Version 1.4

To be filled out prior to the start of the experiment

	Please answer the following questions first	**Yes**	**No**
-	Do you have any metal objects in your upper body? *Exception: dental fillings or crowns.*		
-	Do you have metal fragments in your body, in particular in the eye, e.g., caused by injuries when working with metal?		
-	Do you wear jewelry / piercings that you cannot take off?		
-	Have you had brain surgery?		
-	Do you have an active implant? *(e.g. pacemaker, neurostimulator, insulin pump, ossicle prosthesis)*		
-	Are you using a medical plaster that cannot or may not be taken off? (e.g. nicotineplaster)		
-	Do you suffer from epilepsy?		
-	Do you suffer from claustrophobia?		
-	Are you pregnant or think you are?		
-	Are you younger than 18 years?		

If answered YES to one of the above questions you CANNOT participate in the experiment.

Do you have a metal wire behind your teeth and /or a tattoo?		

If answered YES : The researcher needs to inform you about the risks.

Name: Weight: …… kg.

Date of birth: (dd/mm/yyyy) Length: ……..cm.

Name home physician:

Address :

Note: Only in case of no (Dutch) home physician please check the information of the Academic General Practitioner Heydendaal : www.ugc-heyendael.nl' (see also available information brochure) :

I agree to be informed by the Academic GP in case of a clinically relevant finding YES*

***encircle**

** This form is applicable for research in healthy, competent adults (>18 year). The subject involved needs to provide his or her written consent personally. The questions above only apply for performing an (f)MRI in the head/neck area.**P.T.O***

SCREENING FORM MRI
Version 1.4

To be filled out completely by the RESEARCHER after the experiment

Name : Project number :

Function : Sona systems study name :

Signature : Date :

☐ Payment ……. euro / …….. points

☐ No payment

Reporting of events or findings:

Adverse Event **YES/ NO***

If YES: dd/mm/yyyy time

- Date and time of occurence …….. …….
- 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)**

To be filled out by the PARTICIPANT prior to the start of the experiment:
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; February 2016, version 1.4).
- 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 will be acquired and stored for scientific purposes as mentioned in the general information brochure.
- video and/or audio recordings may take place for scientific purposes.
- I will be informed by my home physician or the academic GP about any new information which is of medical relevance to me.
- I can be approached for a future study.

I understand that:

- I have the right to withdraw from the experiment at any time without having to give a reason.
- My privacy is protected according to Dutch law.
- My consent will be sought every time I participate in a new experiment.

I give my consent to take part in this experiment:

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

Signature:..... Date and place:……

I agree that my experimental and coded data for strict scientific- publication purposes will be shared with others: **YES / NO***

***encircle preference**

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 according to Dutch law.

Name:…… Project code:……

SONA title of the study:……..

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