



## **GENERAL PARTICIPANT INFORMATION**

Version 4.0

With this information brochure, we would like to invite you to take part in a neuroscientific study at the Donders Centre for Cognitive Neuroimaging. Please note that participation is voluntary. In this information sheet, you can read about the study, what it means for you, and what the pros and cons are. It is a lot of information so could you please read the information and decide if you want to take part?

### **Ask your questions**

You can make your decision based on the content in this information brochure. We also suggest the following:

- Ask questions to the researcher who gave you this information brochure.
- Talk to your partner, family or friends about this study.
- Ask questions to the independent expert. Please find their contact information in **Appendix A**.
- Read the information on <https://www.government.nl/topics/medical-research/participating-in-medical-research>.

### **1. General information**

The Donders Centre for Cognitive Neuroimaging (DCCN) has set up this study. Below, we call the DCCN the 'sponsor'. Researchers, research trainees, and/or research assistants conduct the study. The Medical Ethics Review Committee, METC Oost-Nederland, has approved this study.

### **2. What is the purpose of the study?**

The Donders Institute is an academic research centre investigating the function of the brain. The DCCN is sponsor of this study and part of the Donders Institute, which is a collection of centres of the Radboud University and Radboudumc. For our research, we need healthy volunteers (16 years and older) to participate in various studies run by different researchers at the DCCN. These studies include, for example, language, visual, and/or auditory tests, additional stimuli to active relevant brain areas, and methods to measure this brain activity. You can read more about these methods in the method-specific information brochure(s) that you received from the researcher who also gave you this information brochure. The researcher will also inform you about any tasks and procedures you will have to complete as part of the study. All studies and methods are of negligible risk and minimal burden. No invasive procedures are involved.

If you meet any of the following criteria, it is **not** possible to participate in scientific research at the DCCN:

- A history of or current neurological treatment
- Current psychiatric diagnosis and/or treatment
- History of or current brain surgery or epilepsy
- Pregnancy

- Incompatibility with the methods used, this will be asked via a separate method-specific screening form

### 3. What is the background of the study?

Research at the DCCN focuses mainly on the cognitive functions of the brain, such as learning, attention, memory, language, reasoning, and decision-making. The aim is to better understand these complex functions. The centre has several different methods to measure brain activity.

### 4. What happens during the study?

Usually, no extra preparation is required before participation. It is important that you are fit, alert and that you have not consumed alcohol the night before. In addition to this general information brochure you will receive:

1. Method-specific information: here you can read more about the method(s) that will be used in the study : EEG, MEG, (f)NIRS, tCS and/or (f)MRI. Some of these methods have specific criteria, for example that you do not have any metal in your head and/or (upper body). The researcher will screen you on these criteria.
2. Study-specific information: the researcher will provide you with additional study-related information and conditions: e.g., you might be asked to watch a movie or pictures on a monitor, to listen to sounds (via earphones), to perform a task, learn words, make decisions, or to undergo a specific stimulation of the skin.

The researcher will send you all relevant information in a timely fashion, so you can make a well-informed decision about whether you would like to participate. Please read the information carefully. The time investment per study differs from 30 minutes up to a few hours; this includes preparation time and breaks between the measurements.

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. They will explain the aims of the study and the methods that will be used. You will receive instructions about what you are asked to do during the experiment. In all cases, the researcher will answer all your remaining questions concerning the experiment before participation. Once everything has been fully explained, they will ask you to sign the consent form.

### 5. What agreements do we make with you?

We want the study to go well. That is why we want to make the following agreements with you:

- Without your cancellation, we expect you to be on time for the appointment.
- For reimbursement after participation, you must be registered in the SONA system: <https://radboud.sona-systems.com>
- You should contact the researcher in these situations:
  - You are suddenly experiencing problems with your health
  - You do not want to participate in the study anymore
  - Your mobile number, address or email address has changed

If you are pregnant suspect to be pregnant, or there is a possibility that you are pregnant, you **cannot** participate in any of the studies. Do you become pregnant during your participation in a study? Notify the researcher as soon as possible. In consultation with the researcher, you need to stop with participation as soon as possible.

## 6. What side effects, adverse effects or discomforts could you experience?

In general, there are only negligible adverse or side effects known as result of taking part in one of the used methods. You might experience some discomfort while laying flat in the MRI scanner or from the application of electrodes or measuring devices. Before electrodes are attached, the skin will first be slightly degreased with scrub cream, next the electrode will be applied with an adhesive plaster. This procedure might cause a slight, but transient, irritation of the skin. Taking part in an MRI study can induce temporary but transient side effects. This will be explained in the method-specific information brochure. If you experience other effects, these are most likely due to other factors like already having a cold.

## 7. What are the pros and cons if you take part in the study?

Taking part in the study can have pros and cons. We will list them below. Think about this carefully and talk to other people about it.

You do not benefit from taking part in this study yourself, but if you participate, you will help the researchers gain more insight into the function of the brain.

Potential disadvantages could be:

- You may encounter slight discomfort from (extra) measurements during the study. For example, the application of electrodes to measure eye movements or muscle activity.
- You need to follow appointments and instructions as part of the study.

It is possible that an incidental discovery is made during an MRI scan that is not directly related to the research but does concern your health. If the radiologist indicates additional examination is required, you will be informed. The radiologist will advise you about whether you need to consult your GP or a specialist to discuss the next steps. The cost of this will fall under your own health insurance policy. In case you are referred to a specialist, there might be costs involved in the form of the deductible ('own risk'/'eigen risico') of your health insurance. You **cannot** participate in any research at the DCCN if you do **not** want to be informed about a potential incidental finding.

We want to emphasise 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 or screening test.

## 8. When does the study end?

The researcher will let you know if there is any new information about the study that is important to you. The researcher will then ask you if you want to continue to participate.

In these situations, the study will stop for you:

- All measurements according to the schedule are finished and/or the end of the whole study has been reached.
- You have become pregnant.
- You want to stop participating in the study yourself. You can stop at any time. Report this to the researcher immediately. You do not have to explain why you want to stop.
- The researcher thinks it is better for you to stop.
- One of the following national authorities decides that the study should stop:
  - The Medical Ethics Review Committee assessing the study.
  - The research centre (DCCN)
  - The Health Care Inspectorate

*What happens if you stop participating in the study?*

The researchers use the data and body material if they collected any (for example: a saliva sample) that have been collected up to the moment that you decided to stop participating in the study. If you wish, we will destroy the collected body material. Please let the researcher know.

*What happens after the study has ended?*

You can ask the researcher to keep you informed about the research results. Since data analyses and publication are time consuming, it is not feasible for the researcher to agree on a notification term. In general, the researcher will ask you to get in touch over time.

## **9. How will we process your data and body material?**

Are you participating in the study? In that case, you give permission to the researchers to collect, use and store your data and/or biomaterial (for example saliva).

*Which personal data will be stored?*

Contact information: your name, email address, and phone number. No longer than a year after the study is completed for all participants, your personal data will be deleted, unless you give permission to approach you for future research. You can indicate this on the consent form.

*Which other data will be stored?*

Information from questionnaires concerning your personal health and personal features, such as gender, year of birth, handedness, color blindness, etc. and other (health) data that we collected and that are part of the study.

*Why are we collecting, using and storing your data (and biomaterial)?*

We use the data (and if applicable, biomaterial) to answer the research questions from the study. We will share our findings with other researchers in the form of publications.

*How do we protect your privacy during participation?*

To protect your privacy, we assign a code to all your data (and if applicable, biomaterial). The key that links you to this code is stored in a secure place in our research centre. When processing your data (and biomaterial) we only use this code, never your name. In reports and publications about the research no one will be able to trace back data to your identity.

*Who is able to see my information?*

Some people can see not only the code, but also your identifiable information. They check whether the researchers conduct the research in a proper and reliable way. The following people can have access to your identifiable information:

- Members of the committee for safe conduct of research.
- A monitor that works for the researcher or sponsor.
- National regulatory affairs authorities, for instance the Health Care Inspectorate.

These people will keep your information confidential. We ask your consent for them to access your information. The Health Care Inspectorate can access your data without your consent.

*How long will we preserve your research data (and biomaterial)?*

We keep your research data (and if applicable, biomaterial) in the research centre for at least 10 years after study completion. The biomaterial will be preserved to allow additional analyses related to the original research question. As soon this is no longer necessary, the biomaterial will be destroyed.

*Are we allowed to use your research data for other research purposes?*

Your research data are of potential interest for other scientific research to answer additional research questions. Research data are increasingly shared with other researchers or research groups to make the most out of the research data that you spend your time and effort on. This is important to confirm the reliability of the results and increases the efficiency of research. Before we share research data with others, we will remove identifiable features from the data and mask your identity as much as possible. In this way, it will be very difficult for others to trace the data to your identity. Given the nature of certain research data, or the specific combinations of research data, we cannot guarantee full anonymity. For this reason, researchers that receive your data are required to agree to make no attempt to unmask your identity.

If you do **not** agree with the data collection and sharing of your coded and masked research data, you **cannot** participate in this research.

*Audio, video and photography*

Some types of research data, like video or audio recordings, are by nature (directly or indirectly) identifiable. Personal or facial features will be removed as well as possible before the data will be processed for further use. It is, however, not always possible to completely de-identify video/audio recordings which make them potentially traceable to you. For the further use of these recordings you can indicate separately on the consent form whether or not you agree to processing these data beyond the scope of the study you have participated in.

*How about sharing my research data and my privacy?*

Your data will be shared and processed under strict conditions and in compliance with the Dutch and European General Data Protection Regulation (GDPR, AVG). Your name and contact information will never be shared with others unless you indicated on the consent form that you would like to participate in future research. Directly identifiable research data (for example video or audio recordings) will only be shared with others with your explicit consent that you can indicate on the consent form.

*Future research?*

You are requested to indicate whether we can approach you for future research. If you consent, we will store the contact information to make this possible.

*Is it possible to withdraw your consent to use your research data?*

Yes, you can withdraw your consent for us to use your data at any time. This concerns the present study and the use of your data in other research.

Please note: are you withdrawing your consent after the researchers have completed the collection of the data for their study? In that case the researchers have the right to continue to use the already collected research data. The researchers will destroy any collected biomaterial when you withdraw your consent. The results of biomaterials that have been processed and analyzed up to that point may still be used.

*Would you like to know more about your privacy rights?*

For more information about your rights regarding the processing of your personal data, you can visit the website [www.autoriteitpersoonsgegevens.nl](http://www.autoriteitpersoonsgegevens.nl). In case of questions or a complaint, we recommend to first discuss this with the researcher. The DCCN is responsible for the correct processing of your personal data. If you want to discuss this with the Privacy Protection Officer of

the Radboud University, you can send an email to [privacy@ru.nl](mailto:privacy@ru.nl). You can also submit a complaint to the Authority Personal Data.

### 10. Will you receive compensation if you participate in a study?

The payment for each experiment is as follows:

<u>From 18 years and older:</u>		<u>Between 16 and 18 years old</u>	
Behavioural	€ 10 per hour	Behavioural	€ 5 per hour
EEG	€ 10 per hour	EEG	€ 5 per hour
MEG	€ 15 per hour	MEG	€ 7.50 per hour
fNIRS	€ 10 per hour	fNIRS	€ 5 per hour
tCS	€ 10 per hour	tCS	€ 5 per hour
fMRI	€ 15 per hour	fMRI	€ 7.50 per hour
Online testing	€ 7 start fee +		

The Radboud University is obliged to notify the tax authorities about the reimbursement you receive for participation in the experiment(s) at the DCCN. You need to inform the tax authorities about the reimbursement(s) as part of your income tax declaration. We need to provide the tax authorities with: your social security number (BSN), your name, address and date of birth. We will not indicate the reason for the reimbursement, so the tax authorities will know that you participated in scientific research or in which study/studies you participated. You can find more information here:

<https://www.belastingdienst.nl/wps/wcm/connect/nl/home/home>

The DCCN will transfer the payment directly to your bank account within six weeks after your participation. For our administration, we need your bank IBAN-account number, address and BSN.

### 11. Are you insured during the study?

Everyone who takes part in a study at the DCCN is insured via a medical liability insurance and in some cases an additional subject insurance. The insurance pays for damage that is a direct result of participation in the study. It is the case for damage that becomes clear during participation in the research or within four years after the end of the study. You can find more information about this insurance and its exceptions in **Appendix B**. It also indicates to whom you can report damage.

### 12. When will we contact your general practitioner?

We will not inform your general practitioner about your participation in research at the DCCN.

### 13. Do you have any questions?

You can ask questions about the study to the researcher or research team of your study. Would you like to get advice from someone who is independent from the study? Then contact Roel Willems, [r.willems@donders.ru.nl](mailto:r.willems@donders.ru.nl). He knows a lot about the study, but is not a part of this study.

Do you have a complaint? You can discuss this with the researcher. You can also share your experiences via our feedback webform. This form is available here:

<https://www.ru.nl/donders/forms/feedback-webform-dccn-en/>

We appreciate your feedback, and if desired, we will contact you.

#### **14. How do you give consent for the study?**

After you received all the information relevant for the study (see section 4), you will have all the time you need to think about whether you want to participate. You can always ask questions to the researcher. Prior to participation, you will fill out a screening questionnaire together with the researcher. If you would like to participate, the researcher will ask you to sign the consent form.

#### **15. Finally**

If you, for some reason, are not able to get to your appointment in time, please inform the researcher or research centre in a timely fashion. The DCCN reception can be reached via +3124-3610750.

A general information brochure has been developed by the Ministry of Health: “Medisch-Wetenschappelijk onderzoek / General information for the subject”. The brochure can be downloaded from [www.ccmo-online.nl](http://www.ccmo-online.nl). Hard copies of the information brochure are available at the reception area of the Donders Centre for Cognitive Neuroimaging.

#### **16. Appendix**

- A. Contact information
- B. Insurance information

## Appendix A

### Contact information:

Donders Centre for Cognitive Neuroimaging  
Visiting address: Kapittelweg 29, 6525 EN Nijmegen

P.O. Box 9101  
6500 HB Nijmegen  
Tel: 024-3610750



### Independent expert

Dr. Roel Willems: [r.willems@donders.ru.nl](mailto:r.willems@donders.ru.nl)

### Complaints

Feedback form: <https://www.ru.nl/donders/forms/feedback-webform-dccn-en>

### Data protection Radboud University:

Ronals Sarelse: [privacy@ru.nl](mailto:privacy@ru.nl)

### Additional information about your rights:

Privacy: [www.autoriteitpersoonsgegevens.nl](http://www.autoriteitpersoonsgegevens.nl) or [mijnprivacy@ru.nl](mailto:mijnprivacy@ru.nl)

Brochure "Deelname wetenschappelijk onderzoek" (in Dutch):

<https://www.rijksoverheid.nl/onderwerpen/medisch-wetenschappelijk-onderzoek/meedoen-aan-medisch-wetenschappelijk-onderzoek>



## Appendix B

### Insurance text

For participants of all research at the Donders Centre for Cognitive Neuroimaging, a standard medical liability insurance is established.

For some studies, an additional law-imposed subject insurance is established. 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](mailto:Schade@centramed.nl)

The insurance provides a maximum coverage 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 Human Subjects: [www.ccmo.nl](http://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 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.