Procedure MRI

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Aim of this document

This document describes the Procedure for measurement of (functional) Magnetic Resonance Imaging ((f)MRI) at the Faculty of Psychology and Neuroscience (FPN). This procedure has been approved by the Ethics Review Committee of Psychology and Neuroscience (ERCPN) and consists of professional standards for safe, hygienic, and valid (f)MRI measurements. If a researcher explicitly states to adhere to this Procedure in research proposals that are sent to the ERCPN then the ERCPN will generally approve this aspect of the research proposal.

Description of the (f)MRI technique

MRI and fMRI are non-invasive ways to obtain structural and functional information of the human brain. Similarly, MR spectroscopy non-invasively provides information about its molecular composition. These techniques are well-established, safe, and relatively comfortable methods for clinical and research applications. fMRI passively registers hemodynamic activity that is linked to neuronal activity in the brain. All these techniques are noninvasive.

Known persistent side- or after-effects

At FPN, MRI measurements and experiments are conducted at the Scannexus scanner lab which hosts 3, 7 and 9.4 Tesla scanners. The 3 Tesla scanners, which are widely used in research and clinical settings, are considered to be standard and safe. Within scanning parameters used, no negative consequences have been reported. While the 7 Tesla field has been recently cleared by the European Union (CE approval) and FDA, *the 7T scanner at Scannexus is approved (by Siemens) as a research only device, so excluding clinical use*. MRI studies at 7T are rapidly becoming standard. Worldwide, there are more 50 scanners used for human basic and clinical research and no negative effects have been reported. According to the guidelines from the U.S. Food and Drug Administration (FDA), clinical MR systems using static magnetic fields up to 8.0 Tesla are considered “non--significant risk” for adult patients (level was set in 2003) (http://www.mrisafety.com/safety_article.asp?subject=229). More than one thousand examinations were conducted at 4, 7 or 8T, no indications for any lasting health effects on humans have been observed (see, e.g. the publication DOI: 10.1002/jmri.10367). As stated also in de 9.4T Safety paper (Scannexus, C. Wiggens, 2013, the move to 9.4T does not bring any substantial increased risk to participants.

Starting an fMRI study

In order to be allowed to start an fMRI study, a project first needs:

1. an approved scanning budget (actually not an ethical-issue, but a practical one).
2. an ERCPN-approved Research Protocol or Research line, or a Research approval from the Medical Ethics Testing Committee Maastricht (METC).
3. approval from the MRI Project Proposal Committee obtained through the participation in a Project Proposal Meeting (**PPM**).

Combined EEG/MRI studies (or single EEG studies intended to be performed in a MRI lab) need to go through the MRI PPM.

The PPM will check for safety and if formal approval by the ERCPN has been granted. They also provide feedback on study design, acquisition parameters, and data analysis plan.

You will need to provide a code (project/budget number) for your experiment to be used when booking a lab and/ or equipment to keep track of who is using the lab and/or equipment and at which times.

Experimental procedures regarding fMRI studies

1) ***Only a certified user (CU) may operate the MR-scanner.*** CU training is performed by Scannexus, for procedures on how to become certified user, contact (scanlabs@scannexus.nl). Others may only operate the scanner under the immediate and direct supervision of a certified user that has to be present in the room.

2) Participant screening
   The presence of metal in the body (e.g. implants) or specific physiological conditions represent counterindications for participating in MRI studies. These counterindications are reported in a specific screening form (**Screening Form A**) that must be provided to participants in advance or be filled in right before the scan. ***All participants have to be screened for such counterindications.*** In addition, all participants will have to fill and sign a Scannexus specific MRI safety form that will need to be handed in to Scannexus at the end of every scanning session. English and Dutch versions of this safety form can be found at the Scannexus premises.

3) Consenting to participation
   Participants willing to participate, must **first give their consent in writing**. Consent should be given freely, without coercion, and based on a clear understanding of what participation involves. The consent discussion should begin sufficiently in advance of the initiation of study-related procedures to allow potential participants time to reflect on the potential benefits and risks and possible discomforts. ***For (f)MRI studies at FPN a template written consent form is already provided.*** This form includes relevant sections on the treatment of incidental findings.

4) Incidental findings
   Although the data collected during an MRI experiment does by no means represent a comprehensive clinical MRI investigation and is not monitored routinely for abnormalities, it may give indications concerning the health of the participant. When this is the case, the incidental finding procedure is started. The aim of this procedure

is to inform participants if they have potentially clinical relevant findings so that further investigations can be initiated. ***The procedure to be followed for incidental findings is described in the template written consent form. Thus, when applying for approval of your study at the ERCPN, do not write your own incidental findings procedure.***

Safety guidelines and procedures regarding (f)MRI studies

Equipment and Safety Considerations
At all field strengths researchers are only allowed to use specific approved devices (e.g. RF coils; eye trackers) and should follow procedures that have been cleared for use by the Safety Review Board (SRB). If an FPN researcher wants to use a new device or procedure, it has to have received approval from the SRB. A list of all safety approved devices available at the Scannexus facility is available upon request to Scannexus. For doubts or general information FPN researchers can contact the MRI user interface of FPN (currently F. De Martino).

Scanning Protocols and safety guidelines
The 3 Tesla scanners, which are widely used in research and clinical settings, are considered to be standard and safe. Within scanning parameters used, no negative consequences have been reported. While the 7 Tesla field has been recently cleared by the European Union (CE approval) and FDA, *the 7T scanner at Scannexus is approved only as investigational device certified for research*. MRI studies at 7T are rapidly becoming standard. The human body is non-magnetic and therefore the static magnetic field (up to 14 Tesla or more) does not harm biological tissue. The radiofrequency and the MR gradient applied, however, interact with the human body via heating (specific absorption rate, SAR) or peripheral stimulation, respectively. Limits for both of these issues potentially are reached at 7 Tesla for some scanning protocols which are harmless at 3 Tesla. However, *as the same absolute limits apply for both scanners and they are encoded within the hardware of the 7 T system*, certified users will therefore always stay below the limits when using standardized scanning protocols.
Therefore, within the limits of the SAR and peripheral nerve stimulation, 7 Tesla is safe for human research. The move to 9.4T does not bring any substantial increased risk to participants.

Researchers that seek amendments to this general procedure can do so by contacting ERCPN for ethical issues and the Safety Review Board (SRB) of FPN/FHML/Scannexus for safety issues.

More Information and relevant Documents
For more information please consult the FPN MRI user interface intranet page (https://intranet.maastrichtuniversity.nl/en/faculty-psychology-and-neuroscience-employees/fpn-research/fpn-mri-user-interface). In case this is not sufficient please contact the MRI lab coordinator.
Relevant documents including screening forms and written consent forms can be found at **the path: J:ORGANISATION > FPN > FPN MRI user interface**

Addresses

The FPN interface between FPN MRI users and Scannexus (scanner lab coordinator).

- F. De Martino, f.demartino@maastrichtuniversity.nl

Outlook agenda for the scanners

- Public Folders / All Public Folders / Fdp / Onderzoek / MRI (7T, 3T or 9.4T)

Server location for useful MRI lab information

- \\unimaas.nl\Organisation\FPN\FPN MRI User interface\

Ethical approval

- Ethical approval is required for all studies conducted under the responsibility of FPN staff. For details about who must and can apply for approval, see the Online Application Form at the ERCPN site: https://www.maastrichtuniversity.nl/about-um/faculties/psychology-and-neuroscience/facilities/ethical-review-committee-psychology-and