Contents

1. General Information

The Faculty of Psychology and Neuroscience (FPN) believes it is important that scientific research is conducted in an ethically responsible manner. This is all the more pertinent in case of participation by human subjects. Ethically responsible research should meet the requirements of scrupulousness and proportionality. The requirement of proportionality implies that the acquisition of new scientific knowledge bears reasonable proportion to the difficulties and risks for the subject.

Within the FPN, the Ethics Review Committee Psychology and Neuroscience (ERCPN) evaluates based on assessment criteria whether the requirements for ethical research are met, as stipulated in the "Code of Ethics for Research in the Social Sciences involving Human Subjects"[1] and other national, European and international codes and guidelines for scientific research involving human subjects. The code can be found on the website https://www.maastrichtuniversity.nl/about-um/faculties/psychology-and-neuroscience/facilities/ethics-review-committee-psychology-and.

1.1 Members & secretariat 2017-2018

- Prof. dr. Gerjo Kok (chair)
- Dr. Fren Smulders (vice chair)
- Dr. Martin van Boxtel
- Dr. Linda Vancleef
- Dr. Chantal Nederkoorn
- Dr. Kai Jonas
- Drs. Rob de Vries
- Prof. dr. Ger Keijsers
- Marcel Schrijnemaekers LL.M. (secretary)
- Mrs. Annie Hendriks (secretariat)
- Mrs. Jeannette Boschma (secretariat)
- Mrs. Brigit Lok (secretariat)

[1] Drafted by the national conference of ethical review committees Psychology and other social-scientific disciplines at the request of the VSNU (Association of Universities in the Netherlands), and submitted to the Disciplinary Body for Social Sciences (DSW) of the VSNU.

General mail address: ercpn-fpn@maastrichtuniversity.nl

2. Methods of the ERCPN

When reviewing study protocols, the ERCPN uses principles and criteria from the "Code of Ethics for Research in the Social Sciences involving Human Subjects" as described below and in chapter 5 *Filling in the application form step-by-step the application form.*

1. The study is expected to yield new and relevant insights.
2. Subsidiarity: These insights cannot be acquired using a different, less far-reaching approach (e.g. with adult subjects instead of children, less invasive measurements, etc.).
3. Proportionality: Acquiring these new insights bears a proper proportion to the difficulties and risks for the subjects.
4. The study meets the requirements of correct methodology.
5. The study takes place under supervision of an expert.
6. Compensation per subject cannot be too great, as that would interfere with reasonable consideration, and as such voluntary participation.
7. The study meets all other reasonable requirements.
8. Written consent is given by the subject and/or its guardian in advance.
9. The subject may at all times terminate his/her participation in the study. Signals in this regard should be respected by the researcher and, if confirmed, be followed up in the sense of actual termination of participation in the study.
10. The consent is an "informed consent", which means that the subject has been informed in advance about the goal, nature and duration, risks and difficulties.
    Please note that it isn't allowed to use the declaration of consent form as an information letter.
    - Goal: usually described in very general terms, if at all, for the purpose of avoiding bias effects;
    - Nature: the specific nature of what the subjects needs to do, without sharing the goal or any expectation of the experimenter;
    - Duration;

- Risks and difficulties.

11. This information is clear and has been tailored to the subject (e.g. in the case of minors). The subject will be offered time to reflect between information and consent. If complete information in advance proves impossible due to the nature of the study, then the subject should be informed in full afterwards.
12. Minors and subjects without legal capacity should also be informed in all cases in accordance with their level of comprehension.
13. Studies may not take place with subjects that occupy a subordinate position in relation to the researcher, such as supervisor-thesis writer or employer-employee, unless the study can benefit those subjects and cannot be conducted in a meaningful manner with others.
14. The subject's privacy should be respected and protected at all times.
15. All advertisement text should bear the reference code of the ERCPN.

3. Application and notification procedures

The ERCPN differentiates between seven types of application and notification. They are explained below including the action required:

1. Application for a new study – *Fill in the application form;*
2. Application for a (re)new(ed) line of research (comprising more than one study and using the same types of research questions and similar experimental methods throughout) - *Fill in the online application form;*
3. Notification for a new study within a line of research that has already been approved (so called single study) – *Fill in the single study form (see website)*;
4. Application to change a study or a line of research that has already been approved (so called amendment) – *Send an email to the ERCPN (ercpn-fpn@maastrichtuniversity.nl) including all changed documents;*
5. Notification for a study that has already been approved by an ethics review committee comparable to the ERCPN – *Send an email to the ERCPN (ercpn-fpn@maastrichtuniversity.nl) including the approval document;*

6. Application for the extension of a study – *Send an email to the ERCPN (ercpn-fpn@maastrichtuniversity.nl) including all changed documents;*
7. Notification for the (early) termination of a research line – *Send an email to the ERCPN (ercpn-fpn@maastrichtuniversity.nl) that includes both the ERCPN reference number and the research line's title.*

Note:

1. The ERCPN will handle all requests carefully. Applicants are therefore expected to have written their applications with care and an eye too:

a) Language: correct Dutch or English (or other languages if designated for informing and communicating with the subjects);

b) Clarity: the ERCPN consists of relative laymen;

c) Brief comprehensiveness.

2: The use of MRI, NIBS and EEG requires additional formalities;

3: In case of type 3 and 5 notifications, students should always include their FPN supervisor in the email;

4: If possible, researchers are encouraged to submit lines of research. However, in principle, a line of research is not possible for studies that involve the presentation of emotional stimuli.

5: As a general rule, ethical approval will remain valid for a period of one year for studies (with the option to apply for an extension if required) and five years for research lines. Research lines automatically end after 5 years and (if applicable) a new application needs to be submitted. Three months prior to the expiring date, the ERCPN will send you (owner of research line) the first email message to remind you of the fact that your research line will expire soon. Please note that this has also consequences for the ongoing single studies. As soon as the expiring date has been passed, performing a single study under the expired research line is not allowed anymore. The second email contains the message that the research line has been terminated.

6: Approval given for studies conducted by Bachelor and Masters Students will remain valid for the duration of the relevant course, project or thesis.

Schematically:

3.1 Application and notification without the use of MRI, NIBS, or EEG methods:

3.1.1 Research line:

- Submit an ERCPN application comprising:
  - A full description of one experiment (including information letter, debriefing etc.);
  - An overview of the other experiments you intend to carry out.

3.1.2 Study, not part of a research line:

- Submit an ERCPN application.

3.1.3 Study as part of an already approved research line:

- Submit a single study form to ercpn-fpn@maastrichtuniversity.nl

3.1.4 Amendments

- Submit the adjustments in a word file to ercpn-fpn@maastrichtuniversity.nl ;
- When applicable, include the adjusted documents (e.g. debriefing, information letter etc.).

3.1.5 (Pain) stimulation devices:

Researchers must adhere to the device-specific procedures which have been approved by ERCPN.

3.2 Application and notification including the use of MRI, NIBS and EEG methods

Studies, (whether single studies or those comprising part of a research line) that involve MRI, NIBS and EEG, need approval from ERCPN (in relation to the content of the study or studies) and from the proposal project meeting (PPM) committees (with regard to the methodological procedures and parameters). In other words, you must receive approval from both committees before testing can commence.

3.2.1 Research line:

- Submit an ERCPN application form (refer to "Procedures", see 3.2.5) comprising:
  - A full description of one experiment (including information letter, informed consent, debriefing etc.);
  - A broad description of the other experiments you intend to carry out.
- After you have received approval from the ERCPN, submit the research protocol to the relevant project proposal meeting, see section 3.2.6.

3.2.2 Study, not part of research line:

- Submit an ERCPN application form with reference to "Procedures", see section 3.2.5.
- After you have received approval from the ERCPN, submit the research protocol to the relevant project proposal meeting, see section 3.2.6.

3.2.3 Study as part of an already approved research line:

- Submit the research protocol to the relevant project proposal meeting, see section 3.2.6.

3.2.4 Amendments

- Submit the adjustments in a word file to ercpn-fpn@maastrichtuniversity.nl
- When applicable, include the adjusted documents (e.g. information letter, informed consent, debriefing etc.);
- After you have received approval from the ERCPN, submit the amendment to the relevant project proposal meeting, see section 3.2.6.

3.2.5 Procedures

- For MRI: Rules for access to the MR System.
- For TMS/tDCS (NIBS): tCs and TMS safety protocol.
- For EEG: Cap and Electrode Cleaning with Sekusept Plus

3.2.6 Project Proposal Meetings

- Contact person for MRI-related details*: F. Demartino:*
  - Submit an MRI form
- Contact person for EEG-related details: *F.Donkers:*
  - Submit an EEG form
- Contact person for NIBS related details*: T. Schumann*:
  - Submit a NIBS form

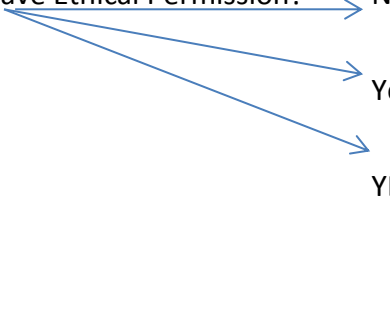
Note: Part of your application to the relevant project proposal meeting involves giving a presentation of your proposal.

3.2.7 PPM Step by step Plan

Actors: Researcher (R), Project Proposal Representative (PPM), ERCPN (mail address)

R: "I want to do a study (MRI, EEG, NIBS)"

PPM: "Do you have Ethical Permission?"



NO: "stop" + refer R to website ERCPN

Yes, METC: ERCPN not involved

YES, ERCPN:

PPM

- Check: study follows ERCPN-recognized Procedure (MRI, EEG, NIBS)? (safety, technical)
- No: "stop"
- Yes:
  - "go"
  - By PPM-form, pass on ERCPN-code + brief description of study to ERCPN

ERCPN

- File as single study (under Research Line or not)
- Occasional check of ERCPN-code:
    - Does study fit the Research Line?
    - Does the Research (line) refer to the relevant Procedure (MRI, EEG, NIBS)?

Proposal for Combined Measurements

Procedures are ordered by Complexity & Risks, so:

MRI-PPM does

- MRI
- MRI + EEG combined
- MRI + TMS combined
- MRI + TMS + EEG combined

NIBS-PPM does:

- TMS
- TES
- TMS + EEG combined
- TES + EEG combined

EEG-PPM does:

- EEG

Other combinations: to be decided ad hoc.

3.2.8 (Pain) stimulation devices:

Researchers must adhere to the device-specific procedures which have been approved by ERCPN.

4. Filling in the application form step-by-step

In general

Are there any ethical sensitive aspects in the current study?

What are solutions?

- Yes: with children, patients, not legally competent
  - Informed consent from parents/caretakers
  - ERCPN members will protect patients' rights: optimal treatment
- Yes: with manipulations that have any negative effect
  - Dealing with negative effects: therapeutic support available;
  - ERCPN members will pilot test all new manipulations or measures
  - Pre-participation information: warnings
- Yes: with intrusive questions
  - Pre-participation information: warnings
- Yes: with privacy issues
  - Protocols for handling data; interview tapes; video tapes; confidentiality and anonymity (problem of anonymity against transparency of data)

First page

Submitting the application form to ERCPN can only be done by:

- Faculty of Psychology and Neuroscience (FPN) PhD scientists.

- PhD students appointed by the FPN.
- Supervisors appointed by the FPN or elsewhere at the UM for the purpose of supervising students of:
  - FPN bachelor's and master's programmes.
  - FHML the mental health care direction bachelor's programme Health Sciences.
  - FHML master's programme Mental Health.

Note:

1. Bachelor's and master's students are not allowed to submit an application form to the ERCPN. For study purposes, a test application form is available on the AskPsy website. (Jan 2018)
2. PhD students can only submit a protocol when they have informed their supervisor.
3. Submitting the application form to ERCPN requires the use of the Maastricht University email address.

[Insert your name and Maastricht University mail-address]

You will automatically receive an email with a unique link, allowing you to leave the application before it is completed and return to it again later.

Section I, number 1

Real Title, not advertisement

Section 1, number 2

Title for recruitment purposes

Section I, number 3

A line of research is a coherent set of studies in which the same types of questions are tested and the same types of experiments are performed. An application for a research line requires a full description of one experiment (including information letter, informed consent, debriefing etc.) and a (broad) description of the other experiments you intend to carry out. You can use section II number 15 for providing the description of the future experiments.

Section II, numbers 9-15

You may only use 500 words or +/- 3.500 characters (including spaces) for the entire section. Any characters exceeding this number will not be stored.

Section II, number 11

Address the following questions:

- What are the independent and dependent variables?
- Does your study have a correlational or (quasi-)experimental design?
- Are human subjects randomly assigned to the different conditions?
- For each independent variable, what design is used: within-groups or between-groups?

Section II, number 14

The ERCPN should be able to evaluate the theoretical, methodological, and societal relevance of the study

Section III, numbers 16 & 17, Section V, number 29

A cover story (deception) can be used if it is important that participants are not informed beforehand of the true nature of the study and what is expected of them. For research purposes, deception can be warranted in order to minimise demand characteristics and reduce the likelihood that participants will provide socially desirable answers. However, it also goes against the principle of active, informed consent. In other words, it is a serious measure that should only be used if really necessary and if appropriate safeguards are put in place, including adequate debriefing after participation. Deception is not allowed in studies

involving minors (< 16 years). Note that deception goes further than not fully informing the participants.

Section III, number 17, last tick box

Please note that it isn't allowed to use the declaration of consent form as an information letter.

- Principle: Active consent
- Passive parental consent: When the study is embedded in an organisation, such as schools, or institutions and active consent would lead to extreme exclusion
- No parental consent: When active consent would lead to extreme selection bias (migrant families/sex education) or active consent is impossible (online survey)

Section IV, number 19

Exclusion criteria need to be standard in advertisement

Section V, number 25

Researchers must adhere to the procedures which have been approved by the ERCPN, e.g. MRI, NIBS, EEG and pain stimulation. Provide the relevant document name (see section 2.3.5 above for MRI, NIBS and EEG).

Section V, number 27

Audio and video recordings contain data, speech and images, which can easily be traced back to individual persons. The use of such recordings - and the (personal) data stored on them - is therefore conditional on guaranteeing (as far as possible) the privacy of those involved in accordance with Research Data management FPN.

This means that participants must be explicitly asked to provide consent for audio and/or video images made for scientific research purposes.
Part of the informed consent process involves addressing:
-The way in which the recordings are stored;
-The person or persons who will have access to these recordings;
-The length of time after which the recordings will be deleted. The maximum period of time

is 10 years after the last publication - but they may be deleted sooner if full transcriptions of the recordings are made.
Archived audio and video recordings can be used for other scientific research purposes if permission from the participants has been granted, or if new consent is granted for this purpose. In cases where renewal of consent is not possible, but the privacy of the involved party can be guaranteed, then it is still possible for the recordings to be used.
You must explain the reason behind the use of any secretly made audio and/or video recordings of the participants.
In case students are involved in analyzing/scoring audio and video recordings, students are obliged to sign the Student Employee Confidentiality Agreement. This agreement can be obtained from the ERCPN's website. Furthermore, the researcher is obliged to describe how analyzing/scoring recordings by students will be organized in order to be able to fulfill the conditions for both supervisor and students as described in the signed contract.

Section VI, number 31

Compensation given to subjects for participating in research cannot be too great, as this could impair judgement about participation, raising concerns about whether participation is truly voluntary.
The FPN generally awards a maximum of EUR 7.50 per hour in cash or gift vouchers, or (for students) one research participation credit or entry into a raffle for a predetermined gift / amount of money. When participants are entered into a raffle, the content of the prize, the chances of winning, and the way in which participants will be notified should be announced in advance. The researcher must ensure that there is a fair method of selecting winners. In special cases, the combination of a fixed individual reward alongside entrance into a raffle is permitted by the ERCPN. You need to explain the reason for this. In the explain section you also need to describe the nature of the gift or raffle prize.
If the participant decides to withdraw from participation in the study at any time, s/he will still receive the full and pre-specified amount of compensation. If multiple payments or rewards are used for repeated measurements, these will be awarded in proportion to the number of times the individual has participated.

Participation credits are registered via the Research Participation System (also called SONA) https://maastricht-fpn.sona-systems.com. Researchers (and students) need to comply with the rules and regulations of SONA.

Section VI, number 32

When a cover story (deception) has been used (section V, number 29), debriefing (verbal and written) should take place as soon as the subject has taken part in the study. Subsequently, after being informed about the true nature of the study, the subjects have the right and should be given the opportunity to withdraw their data if possible. Debriefing is also required if the purpose of the study has not been explained beforehand, or if the information provided was incomplete. The explanation should be given in plain language, with emphasis placed on the actions of the participants and/or what was asked of them and why.

Section VI, number 34

The subjects' privacy should be respected and protected at all times. Personal data (all data that can be traced back to individuals directly or indirectly) and research data should be stored in accordance with Research Data management FPN. Personal data may not be kept longer than is necessary to the ongoing study. An exception to this rule is when subjects have given approval for their personal data to be retained for a longer period of time and for a clearly defined purpose - follow-up studies, for example. Raw study data (completed questionnaires and other scoring lists) must be kept for at least 10 years after publication.

The difference between confidential and anonymous data storage; storage of personal data:

- Anonymous storage means that study data can in no way be traced back to the subject. That means there are no links (through numbers or other forms of encryption) to the personal data of subjects and the data cannot be used to identify the subject that it relates to. Anonymous storage is preferable to confidential storage.
- Confidential storage includes traceability. That means that study data can be traced back to the subject.

Section VI, number 35

Generating individual data in and of itself is rarely the purpose of research. In general it is undesirable because there are often no criteria for interpretation.
In case a problematic individual result is found outside the normal range; participants may be informed but only if there was related informed consent; see for example the fMRI procedures and protocols.
A general advice for professional diagnosis can be given to all participants.

Section VII

Your application needs to be supported by documents. You can upload them here.
The documents mentioned under numbers 36, 37, 38 and 39 are mandatory for each study protocol. Note that the information letter for subjects and the debriefing require the name and mail address of the applicant (responsible researcher). After uploading each document, the relevant check mark will appear automatically. By unticking the check mark, you can still change what will be uploaded.

The maximum size of any file is 20 MB.

5. From submitting the protocol to the decision

1. A protocol is submitted to the ERCPN by the principal researcher.
2. The ERCPN secretariat will check whether all necessary documents are enclosed and filled in. The secretariat will consult the principle researcher in case of questions.
3. The deadline for application is Monday before the ERCPN meeting (see website for dates). Note that per meeting only 20 protocols will be reviewed.
4. The ERCPN's decision can be the following:
    - Approved: There are no objections to the conduct of the study and the research may commence.
    - Not yet approved: There are objections to the conduct of the study and the principal researcher is invited to submit a revised application or an ERCPN delegation will consult the applicant, after which he/she will have to submit a revised application.

    Note:

    1: The principal researcher should provide the ERCPN reference in all correspondence.

2: Advertising as part of the study protocol may only commence after having received an approval.

3: Single studies and amendments are reviewed by ERCPN's executive board outside the regular meetings.