

Theme-coordinators summary fMRI-blueprint

General

- 1. Name of researcher(s)
- 2. Title proposal
- 3. Supervising NIC Principle Investigator

Research question(s)

- 1. What is/are the main question(s) that will be answered / hypotheses that are tested in this research?
- 2. What is the novelty of the proposed research/ how does it extend previous studies?
- 3. Was any pilot investigation done? If yes: what were the results?

Design and subjects

- 1. What is the task and design? Why have you chosen this specific task and design (block/event-related, number of repetitions etc)?
- 2. How many subjects/patients will be investigated?
- 3. Describe the availability of the subjects/patients.
- 4. How do you know that this design has enough power to answer your research question?
- Or: what is the rationale behind the number of subjects and the number of repeated tasks?

Technique

- 1. Why is the main research question best investigated with fMRI? Is there an alternative method available to answer the research question(s)?
- 2. Are any additional techniques involved and if so, are they available?
- 3. Does the executing researcher have hands-on experience with fMRI? If so, what software packages have been used?



METc

In the Netherlands, medical research with human subjects must be judged and approved by an acknowledged institutional review board (METc). In order to determine whether your research is *medical research*, answer the following questions:

1. Does the research involve participants selected on the basis of a medical diagnosis (i.e., patient populations)?

(please answer the question by adding an 'X' in front of the appropriate answer:)

___Yes ___No

2. Is the research project aimed to directly address a medical question, i.e. questions directly aimed at enhancing scientific knowledge regarding the physical or mental health of the population studied?

____Yes ____No

- 3. Does the research project include participants who are not fully able or not allowed to freely decide for themselves whether they want to participate in the study (e.g., children or prisoners)?
 - ___Yes ___No
- 4. Does the study contain invasive procedures, or procedures/manipulations involving psychopharmaca, painful stimuli, potentially distressing/dangerous stimuli (mentally or physically), or procedures that potentially have adverse health consequences¹?
 - ___ Yes No
- 5. Are there clear ethical issues involved with the proposed research project (e.g., heavy social pressure, DNA sampling, blood sampling)?

___ Yes ___ No

If the answer to any of these questions is "yes", METc approval is obligatory.

Send the completed proposal to : Hedwig van Oosten h.p.w.m.van.oosten@med.umcg.nl

¹ If there are indications that health consequences cannot be excluded (e.g., TMS), METc approval is necessary. All EEG and fMRI studies require approval from the NIC Theme Coordinators (TC) who will check these guidelines in consultation with two independent expert reviewers and decide whether additional METC approval is required.