

Internal evaluation procedure for basic (f)MRI studies at the LIBC

Definition basic (f)MRI studies:

- Not subject to Medical Research Involving Human Subjects Act (WMO): 1. Not concerning medical scientific research *and* 2. the procedures and rules of behavior for the participants are limited in scope¹
- Involving healthy human participants ≥ 7 years of age
- Using standard scan protocols at the LIBC (no contrast agents)²
- Risks for participation are negligible

¹See [CCMO](#)

²The CEP evaluates the scope and burden of the intervention/manipulation in the context of the study design and in relation to the relevance of the research; in case of doubt if the study falls under basic MRI, please consult the CEP

Criteria for internal evaluation

Basic (f)MRI studies can be **evaluated internally at the Institute of Psychology**. The internal evaluation is based on the evaluation of the CEP and that of the Research Committee (assessment criteria are described below). Researchers could consult the CEP to check if their planned study is indeed considered as a basic MRI study in case of doubt. If the CEP thinks it is necessary and/or is in doubt whether a study can be considered as a basic (f)MRI study, researchers may be referred to the local METC for either a preliminary screening to determine whether the study is subject to the Medical Research Involving Human Subjects Acts (WMO) or a review of the research protocol for compatibility with the Medical Research Involving Human Subjects Act.

CEP – Additional standards for basic (f)MRI studies

For basic (f)MRI studies, the following standards must be met in addition to the regular standards according to the CEP guidelines:

Incidental findings – Participants need to be informed sufficiently about the procedure related to incidental findings prior to participation. Participants need to be informed that: 1. the acquired images will not be actively checked on incidental findings; 2. there is a chance (albeit a very minimal one) that during the scanning procedure or data analyses incidental findings could occur; 3. If relevant, the GP of the participant will be notified about the incidental findings after consultation with a radiologist. This means that the investigator needs to acquire the contact information of the participant's GP.

Code of conduct – Investigators are required to adhere to the [code of conduct](#) relating to expressions of objection (by minors). Minors (<16 years of age) who are naïve to the MRI scanner are required to undergo a practice session in the dummy scanner before undergoing the experimental session. Researchers are required to submit a protocol describing the procedure for the practice session in the dummy scanner.

Research Committee – Assessment criteria

1. Relevance of the research for the Institute of Psychology.
2. Quality & methodology (e.g. sample size, research question, general procedure, independent/dependent variables, instruments, primary analysis).
3. Feasibility: in the rare case that there are strong limitations in the available scan slots, LIBC and the Research Committee will evaluate the feasibility and planning with the departmental chairs.

Internal evaluation procedure for basic (f)MRI studies

To start the evaluation procedure, researchers need to:

1. submit their study protocol via the CEP tool using the basic (f)MRI template from the drop down menu. **Applications for basic (f)MRI using other templates will not be evaluated by the CEP.**
2. send an **email with a request for internal evaluation with their CEP code and title** to ethiekpsychologie@fsw.leidenuniv.nl.
3. After submitting the basic (f)MRI template please download it and send the document through [email to the Research Committee](#) of the Institute of Psychology (to be able to start the study, approval of the CEP and Research Committee is mandatory).
4. The same submission procedure applies for a revision round.

The turnaround time for these applications is approximately six weeks. In case of doubt if the study falls under basic (f)MRI, please consult the CEP via email.

To initiate an (f)MRI study at the the LIBC, always follow these 8 steps on the [LIBC support page](#). Step 3 'Ethical approval' can take place in parallel to earlier steps indicated by the LIBC support.

Financial approval

For all (f)MRI studies, a financial approval by the unit's scan coordinator needs to be submitted to the LIBC support. Please provide the necessary information to your scan coordinator to allow for this approval. After approval, the scan coordinator will submit the financial approval letter to the LIBC support via email and copy the research director in this communication.