

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 submit their study protocol via the **CEP tool** and then send an **email with a request for internal evaluation with their CEP code and title** to ethiekpsychologie@fsw.leidenuniv.nl. 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.

Below the steps are detailed for initiating a basic (f)MRI study at the LIBC.

Before ethical approval:

1. **Contact the LIBC support team.** The very first step is to **contact the LIBC support team** by sending an email to supportlibc@lumc.nl and let them know that you are planning on starting up an fMRI research project. The LIBC support team will inform you about all (practical) steps that should be taken before starting your project. Important things such as scanning time are all arranged via the stakeholders.
2. **Become a LIBC member.** If you are not a **member** yet, please go to [this website](#) and fill out the membership application form.
3. **Scan license and liability insurance.** Everyone who wants to enter the scanner room, has to take part in the **LIBC safety training** first. The main researcher is allowed to sign up before obtaining ethical approval. You can sign up right [here](#). After taking part in the safety training, you are ready to assist a license holder of another project as a scan buddy. You will be trained to become a license holder yourself.

But before you take part in the training, you have to make sure your **liability insurance** is covered. Please check our online questionnaire (in [English](#) or in [Dutch](#)) to check whether you are fully covered or not. Please note that if you are not fully covered and we need to arrange a LUMC contract for you, it can easily take up to 4-6 weeks to arrange everything. You cannot take the exam to become a license holder if your insurance is not taken care of. So, make sure you arrange this in time.

4. **Ethical approval.** This step can take place in parallel to the steps above. You can submit your study protocol via the CEP tool and send an email to request for an internal evaluation by including your CEP code and title to ethiekpsychologie@fsw.leidenuniv.nl to start the evaluation procedure. The turnaround time for these applications is approximately six weeks. The same submission procedure applies for a revision round. After approval of your application, you will receive an approval letter from the CEP via the usual way.
5. **LIBC approval.** You can submit your protocol and CEP approval by sending an email to the LIBC support team (supportlibc@lumc.nl). The **LIBC board** will review your protocol on technical work ability with our scanner and equipment in mind. Experts from the LIBC will give you additional advice where needed.

After ethical approval:

See [here](#) for the procedure that follows the ethical approval.