

## ORahs MRI Protocol Procedures

### Purpose:

The following guidance has been developed to assist researchers who conduct studies in the Brain Imaging Center (BIC) using fMRI procedures and to assist with the IRB protocol review of these studies. Please note not all risks/safeguards are relevant to all studies:

### 1. ORahs Protocol Subjects Tab - Screening Criteria

Always use the Brain Imaging Facility approved screening form and upload the most current screening form to the Attachments Tab. Provide a list of all exclusion criteria in the Attachments Tab, as applicable.

- I) For studies that include louder MRI sequences, longer (e.g., 2 hours or more) and/or multiple daily sessions, the following additional requirements should be addressed in the protocol:
  - a. Screen for participants with hearing sensitivity (e.g., sensitivity to loud noises, hyperacusis) and/or history of tinnitus and exclude if the protocol involves longer (e.g., more than 2 hours) or daily sessions and/or louder sequences.
  - b. Ensure both the researcher and participant understand the definition of 'tinnitus'. Define 'tinnitus' (e.g., ringing, clicking, buzzing in one or both ears that may be constant or may come and go) as participants may not understand what this means. For example, PIs should consider if a participant sometimes gets ringing in their ears, whether this would be considered a history of tinnitus and should the individual be excluded from participation.
  - c. Exclude participants with self-reported hearing loss or sensitivity, unless cleared by their physician or based upon other justifiable criteria.
  - d. Screening for chronic migraines and previous excessive noise exposure (e.g., job-related noise exposure) and exclude participants if appropriate based on the study design).
    - i. Exclude participants on any of the above items (a-d) based on the study design and participant's history.
- II) Provide a clear description of exclusion criteria in the Subjects Tab under the "inclusion/exclusion criteria" section for what types of health histories screened for would exclude potential individuals from participating in the research.

### 2. ORahs Protocol Procedures

***In lay terms***, clearly describe each type of planned MRI scan, the length of time for each scan including total amount of scanning time and estimated decibel range for each scan.

- a. For single or routine sessions, reference that the most current BIC Facility standard operating procedures will be followed.
- b. For daily/repeated/multiple scanning sessions, the scanning sessions summary should be provided as an addendum in the Attachments Tab. This will assist the IRB in evaluating risks and determining if additional safeguards are required.

- i. Indicate who will be performing the MRI scans. If the scans will be performed by anyone other than the BIC facility technologist or the faculty PI, describe how the MRI researcher/operator and how they are is/will be trained.

### 3. ORahs Protocol Risk/Safeguards

- a. Psychological Risks/Safeguards – Include claustrophobia as a risk and the use of a “panic button” as a safeguard. Instruct participants that they may use the “panic button” for anything at any time. Include safeguard for early termination (i.e., use of the “panic button” for claustrophobia is criteria for early termination).
- b. Physical Risks/Safeguards – Include the following risks and safeguards:
  - i. Metal – MRI scanners attract certain metals which may be harmful to a participant. Describe the risks of metal and the screening used to safeguard against these risks.
  - ii. Pregnancy – Unless specifically approved by the IRB under 45 CFR 46 Subpart B and while there is no evidence that an MRI scan is harmful to a fetus, all studies involving MRI scans, women of child-bearing potential must be excluded from participation based on the self-reported screening.
  - iii. Hearing - Provide an estimated range of noise exposure in decibels for the specific scanning sequence to be used that will occur during the study. Provide estimates concerning the severity and frequency (probability) of hearing damage, and, as needed, address differences in risk associated with multi-scanning or dense-sampling studies (that is, the risks for multiple sessions should not be the same as the risks for a single session – for example, the probability of hearing damage will be greater with repeated sessions, longer sessions, and so on).
  - iv. Abnormalities – Since MRI scans are routinely employed in clinical practice, it is important that subjects not confuse a research scan with a clinical scan. The protocol should include a plan for dealing with incidental findings and participants should be fully informed of who will report such findings to them. See example protocol and consent form language below.
  - v. Peripheral Nerve Stimulation – Provide a brief description of peripheral nerve stimulation and proposed safeguards (e.g., stopping the study if reported by the participant).
- c. Autonomy Risks/Safeguards – For any studies that involve lab members, peers, employees, or students of the research team, especially when the study involves multiple scans and/or higher risk activities include methods for reducing risks to autonomy.
  - i. PIs will be required to justify the use of participants where there is a heightened risk of coercion and why other subject populations cannot be used.
- d. Other Risks/Safeguards – Adverse Event Management
  - i. Indicate the procedures in place for dealing with medical emergencies or incidents that might arise during the study. The procedure should include the

following: (1) who will be notified, and (2) if not available, who can serve as back-up, and (3) training on injury reporting.

- ii. Criteria for terminating a study session for greater than minimal risk studies - Ensure all research team personnel are informed and trained on standard criteria for halting a study session (e.g., if a participant has a headache, ears hurt, ear plugs not fitting properly, feel dizzy or lightheaded, and so on)

#### **4. ORahs Consent Tab – Elements of Informed Consent**

Ensure the following optional elements of informed consent are selected and included in the Consent Form language:

- a. Optional Elements: 15, 18, 19, 20, 24, 25
- b. Optional Elements: 16 (this option is only required to be selected only if the study is considered greater than minimal risk)

#### **5. ORahs Consent Forms Tab – Creating a Consent Document**

Ensure that the following items, such as risks and appropriate safeguards, are communicated to research participants. Use first-person language and an appropriate reading level (e.g., eighth-grade for adult participants)

- a. Describe the MRI scan and what an MRI does (e.g., an MRI is a special three-dimensional picture of the brain using magnetic and radio waves).
- b. Describe that while it is commonly used in medicine for the purpose of diagnosing abnormalities of the brain, the procedures that are to be used in the study are different from MRI scanning used in medicine. Indicate that the procedures and scanning sequences are experimental, do not contain clinically relevant information and there is no intention to make any medical diagnosis with the MRI as used in this research setting.
- c. Describe what will occur if incidental abnormalities are discovered from the limited scanning sessions.
- d. Include the following risks and describe appropriate safeguards:
  - i. Metal;
  - ii. Child bearing potential;
  - iii. Hearing and potential decibel exposure;
  - iv. Peripheral nerve stimulation;
  - v. Claustrophobia;
  - vi. Abnormalities;
  - vii. Confidentiality/privacy and data sharing with others
  - viii. Risks to autonomy (if using lab members, peers, employees/subordinates of the research team)
- e. Describe under what circumstances that either the subject or investigator may terminate the experiment (e.g., fatigue, signs of distress, headaches, ringing in ears, etc.).

#### **6. ORahs Protocol Attachments**

Provide a copy of all relevant attachments in the Attachments Tab, including:

- a. BIC Facility Screening Form
- b. Other screening forms based on the nature and duration of the experiment
- c. CA Experimental Bill of Rights - per CA Law, all participants undergoing a “medical procedure” must be provided with the CA Experimental Bill of Rights included in the subject’s native language with the informed consent documents.
- d. MRI Addendum for longer or multiple sessions

## 7. IRB Determination of Risk/Review Level

Studies that involve MRI procedures and present no more than minimal risk to subjects may sometimes be reviewed by the expedited process if they fit in one or more categories listed in the federal regulations.

The Human Subjects Committee has determined MRI procedures to be *greater than minimal risk* whenever the device is employed for research purposes *if intravenous contrast, sedation, or drugs are also being used*, since the probability and magnitude of harm or discomfort anticipated in the research is greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [45 CFR 46.102(i)].

MRI studies may also be deemed *greater than minimal risk* if the functional challenge/intervention or the physiological or psychological stimulation is such that the probability and magnitude of harm or discomfort anticipated in the research is greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

For studies involving normal, healthy subjects in which no sedation, drugs, or contrast are used, the study may be deemed to *present no greater than minimal risk*, as the probability and magnitude of harm or discomfort anticipated in the research is not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Studies that involve recruitment of individuals who are friends, lab members, students, employees/subordinates of the research team, especially when the study involves multiple scans and/or higher risk activities, strong justification and safeguards will be required for recruiting participants with personal/ subordinate relationships to the research team, as it may be impossible to adequately mitigate the risks to autonomy (the IRB may not approve the subject recruitment plan).

MRI studies involving children may be approved under 45 CFR 46.404, for “research not involving greater than minimal risk to the children.” However, these studies are generally reviewed by the full committee initially, and may also go to the full committee at the time of continuing review.

For studies that involve *greater than minimal risk*, or include long and/or multiple scanning sessions, recruiting from friends, lab members, etc. the IRB may require post-approval monitoring requirements, such as daily wellbeing checks, identification of a neutral third party, observation of the informed consent process, or may include other requirements necessary to protect research participants.

**References:**

UC Berkeley Magnetic Resonance Imaging (MRI) in Research