MAGNETIC RESONANCE IMAGING (MRI) IN RESEARCH

This guidance document is intended for investigators using MRI in research. Should you need additional assistance, please contact OPHS at 510-642-7461 or ophs@berkeley.edu.

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A. Introduction

The following guidelines reflect standard procedures accepted by CPHS for UC Berkeley studies involving magnetic resonance imaging (MRI), functional MRI (fMRI), and magnetic resonance spectroscopy (MRS), as well as how such procedures should be described within the study protocol narrative. These guidelines apply to commercial, FDA-approved magnetic resonance instruments. Studies employing specialized, non-conventional instruments will be reviewed on a case-by-case basis by CPHS.

Screening: (*The protocol should reflect the following information (under "Screening," "Procedures," "Risks/Discomforts," etc. as applicable.*)

Because of the high magnetic field of the MRI scanner, individuals with pacemakers, metallic implants, or certain other conditions should be excluded. Each potential subject must fill out a questionnaire to identify these possible contraindications to MRI scanning. Also, because the MRI scanner attracts certain metals, precautions must be taken to remove metallic objects from the MRI room. As an additional measure of protection, a metal detector should be in place to screen subjects before entering the scanner.

Pregnancy Exclusion: While there is no current evidence that an MRI scan is harmful to a fetus, it is the policy of the CPHS that for all studies involving MRI, fMRI, or MRS, subjects who are able to become pregnant must be excluded from the study if a pregnancy test is positive or if the subject or subject's parent thinks that they might be pregnant.

In all cases, recruitment and consent materials should warn prospective subjects that pregnancy is an exclusion criterion for the study. See Part B below for specific recommended consent, assent, and permission form language

(Note: These requirements do not apply to those who have not yet begun menstruating and those who are post-menopausal.)

Risks/Discomforts: The CPHS accepts current evidence suggesting that, in most cases, MRI is a minimal risk procedure. However, as above, the protocol should note under "Risks/Discomforts" that because the

MRI scanner attracts certain metals, it could move metallic objects within the MRI room, which might harm a subject. It should also note that individuals with pacemakers, permanent cosmetics, or certain metallic implants will be excluded, as will those with a history of claustrophobia.

This section of the protocol should also discuss that although MRI scanning itself is painless, subjects may experience discomfort. Some people become claustrophobic inside the magnet. Also, subjects may be bothered by the beeping and hammering sounds made when the scanner is collecting measurements, and/or experience peripheral stimulation, manifested as a gentle tap or sensation of mild electric shock. (Note: The latter should be explained in lay language in the consent form; see example below, under "Recommended Consent Form Language").

Measures to minimize risks/discomforts: The protocol should provide for and should indicate the following: (1) Screening procedures will be used to exclude any subjects who have metallic objects in their bodies, have a history of claustrophobia, or have other MRI contraindications. (2) Subjects will be informed that they may terminate the session whenever they feel discomfort for any reason. During MRI scanning, subjects will be able to communicate with the investigators via an intercom system, so that any anxiety or discomfort can be immediately addressed and scanning aborted if necessary. (3) Disposable earplugs or other ear protection will be provided to diminish the noise.

Currently unknown risks/discomforts: Per discussion above, as a precautionary measure to guard against unknown risks to fetuses, pregnant subjects must be excluded from participation.

Adverse Event Management: The protocol should indicate the procedures in place for dealing with medical emergencies or incidents that might arise during the study. This procedure should include the following: 1) The physician in charge will be notified immediately, and the lead investigator, if not present, will also be notified. 2) In the case that the physician in charge cannot be reached, the Tang Center or other appropriate medical facility will be notified immediately. To prevent any confusion regarding this, the plan for managing such emergencies should be visibly posted in the facility.

"Incidental" Medical Findings: Since MRI scans are routinely employed in clinical practice, it is important that subjects not confuse a research scan with a clinical scan. Consent language (see below) should make clear that the research scan is not a clinical scan (i.e., it is not being done for clinical diagnosis or treatment), so the subject does not infer that the scan is meant to confirm or rule out a medical problem. On the other hand, participants should be informed of the possibility that an abnormality could be detected or suspected in the process of the research, the clinical significance of which may not be clear.

The protocol should include a plan for dealing with incidental findings, and participants should be fully informed as to what the policies and procedures for such incidental findings are. This plan should identify appropriate personnel or consultants who will report such findings to the participants and/or their physicians. If a physician is involved in the study, he/she would be an appropriate informant. In non-medical settings, the lead investigator or other responsible and qualified individual may be an appropriate person to serve in this role.

B. Recommended Consent Form Language

The following sample statements reflect commonly used language in UC Berkeley consent forms for studies involving fMRIs and should be adapted as necessary for other MRI techniques. All consent statements should accurately reflect the procedures described in the protocol.

Procedures: "fMRI" is an abbreviation for functional magnetic resonance imaging, a procedure that is described in more detail below. If you agree to participate, you will be asked to complete an MRI Contraindications Screening Sheet. This screening sheet contains questions that allow us to determine whether you can safely participate in this study.

For subjects under 18 years old: Both the child's assent form and the parents' permission form must include wording such as, "There is no current evidence that an MRI brain scan is harmful to a fetus. However, as a precautionary measure, we recommend that pregnant subjects do not participate in this research study. If there is any chance that you are [your child is] pregnant, you [they] should not participate in this study. Should you [your child] be concerned about the possibility that you [your child] might be pregnant before participating in the experiment, we will have a pregnancy testing kit that you [your child] can administer in private; you [your child] will not be required to reveal the results."

For subjects 18 years or older: The informed consent document should include wording such as, "There is no current evidence that an MRI brain scan is harmful to a fetus. However, as a precautionary measure, we recommend that pregnant subjects do not participate in this research study. If there is any chance that you are pregnant, you should not participate in this study. Should you be concerned about the possibility that you might be pregnant before participating in the experiment, we will have a pregnancy testing kit that you can administer to yourself in private; you will not be required to reveal the results."

Following completion of the screening procedures, if you qualify, you will be asked to have an fMRI scan. The MRI scanner measures small changes in magnetic fields produced in your brain and generates images of the human brain. An fMRI is designed to detect small changes in blood flow associated with activity in various parts of the brain. You will be asked to lie down on a platform that can be slid into the center of the magnet. A plastic coil will be placed around your head and foam pads will be placed to limit head movement during the study. You will then be slid into the magnet and asked to lie still for approximately 60-90 minutes, during which time MRI images will be acquired. At different points during the scan, you will be asked to perform cognitive tasks [*provide description*]. You will be given a break from performing the tasks every 5-10 minutes. You can take breaks more frequently if you want.

Risks/Discomforts: While there are minimal risks from MRI as it is to be performed and MRI scanning itself is painless, participation may involve some discomfort. In particular, you may be bothered by the loud noise during the study that is due to beeping and hammering sounds made when the scanner is collecting measurements. Disposable earplugs will be provided to diminish the noise. Also, some people become claustrophobic while inside the scanner. (Individuals with a history of claustrophobia will be excluded from the study.) You may also experience stimulation of the nerves in your body, which feels like a gentle tap or sensation of mild electric shock.

We will be able to communicate with you during the session via an intercom system. If you feel uncomfortable in the scanner for any reason, please let us know and we will stop the experiment.

The magnets in the MRI scanner are extremely powerful and will attract any metallic objects brought into the MRI room, so you must be careful to leave anything made of metal outside the room. People with pacemakers, or certain metallic implants in their body cannot participate in this study. You will be screened for these conditions.

This study is part of a research protocol and is not intended to provide a comprehensive clinical MRI examination of the brain. Your MRI scan will not be read by a radiologist. However, if a potential

abnormality is identified on your MRI scan, you will be notified and your scan will be forwarded to a physician of your choosing upon your request.

C. Determination of Risk/Review Level:

Studies that present no more than minimal risk to subjects may sometimes be reviewed by the expedited or exempt review process if they fit in one or more of the categories listed in the federal regulations. All studies involving greater than minimal risk of harm or that do not otherwise qualify for exempt or expedited review require review by the convened Committee (full board review).

CPHS 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.

Some 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 full committee at the time of continuing review.

**Note*: Under California state law, minors are those under 18 years old; however, if the study is carried out in other states or countries, local law may prevail.

For further information regarding the above, please contact the Office for Protection of Human Subjects (OPHS) at (510) 642-7461 or visit our website at: http://cphs.berkeley.edu.

MRI Contraindications Screening Sheet

Date: _____

Subject ID: (to be completed by investigator; do not write subject name) _____

Gender: M / F

Yes **No** 1. Do you have any metal in your body?
If yes, describe: _____

Yes **No** 2. Do you have any metal plates__, pins__, wires__, screws__, a joint replacement__, or anything that might have been inserted during an operation/surgery__?
If yes, describe: _____

Yes **No** 3. Do you have an artificial limb?
If yes, is it removable? _____

Yes **No** 4. Have you had heart or blood vessel surgery**?**
If yes, do you have any of the following: pacemaker__, cerebral arteriogram__, stent__, or any metal implants related to the heart or blood vessel surgery__?

Yes **No** 5. Have you ever worked with metals (e.g. metallurgy, metal shaving, welding, soldering, etc.)?
If yes, describe: _____

Yes **No** 6. Have you ever been injured as a result of metal work?

Yes **No** 7. Have you ever been wounded by anything metal, e.g. a bullet, shrapnel, metal filing?
If yes, describe: _____

Yes **No** 8. Have you ever gotten a piece of metal in your eye?

Yes **No** 9. Do you have hearing problems?
If yes, do you have any of the following: Hearing aid__ (If yes, removable__ non-removable__), cochlear implant__, ear surgery_____?

Yes **No** 10. Are you wearing any cosmetics today?

Yes **No** 11. Do you have tattoos or permanent cosmetics (lipstick, lip liner, eye liner**)**?

Yes **No** 12. Do you have any piercings?

Yes **No** 13. Do you wear colored contacts?
If yes, do you also have non-colored contacts? _____

Yes **No** 14. Do you have dental bridges or dental plates**?**
If yes, are they removable? _____

Yes **No** 15. Do you have metal dental caps? If yes, approximately how many? _____

Yes **No** 16. Do you have any non-removable metal in your mouth besides fillings?
If yes, describe: _____

Yes **No** 17. Do you have fillings? If yes, how many? _____

Yes **No** 18. Have you ever been told you can't have an MRI or fMRI for any reason?
If yes, what was the reason? _____

Yes **No** 19. Have you ever been claustrophobic or afraid of small spaces?
If yes, describe: _____

If you are able to become pregnant:

Yes **No** 1. Do you understand that if you are pregnant you should not participate in the study?

Yes **No** 2. Do you have an IUD? If yes, what type? _____

Signature of person administering screening: _____