

Standards and Language for Studies Involving MRI

This document reflects standard procedures accepted by the University of Colorado Boulder IRB for studies involving magnetic resonance imaging (MRI) and functional MRI (fMRI). It provides guidelines for how to describe the procedures in the protocol and consent form. These guidelines apply to commercial, FDA-approved magnetic resonance instruments. Studies using specialized, non-conventional instruments will be reviewed on a case-by-case basis by the IRB.

A. Protocol Standards and Language

The protocol should include the following information under an appropriate section – About the Subjects, Procedures, Risks to Participants, etc.

1. SCREENING and MR PROCEDURES.

The magnetic field of the MR environment has the potential to cause burns or bodily injury if ferrous metal objects are implanted in the body or if personal articles containing ferrous material are brought into the environment. The protocol must specify how participants with contraindications for MR studies (internal/implanted defibrillator or pacemaker, surgical brain aneurysm clips, cochlear implant, or known metal fragments embedded in the body) will be excluded. The protocol must specify how participants with medical or electronic devices that may interfere with the exam or pose a risk will be evaluated and how risks to these participants will be minimized. Examples of such devices include but are not limited to: artificial heart valves; implanted drug infusion ports; artificial limbs or metallic joint prostheses; implanted nerve stimulators; metal pins, screws, plates, stents or surgical staples.

For studies where minors will be scanned, parents/guardians may not have knowledge of the minor subject's complete health history. For example, minors can consent to certain medical procedures, like requesting birth control procedures, supplies or information (CRS §13-22-105). On the other hand, a minor may not have knowledge of their own complete health history, so parents/guardians should not be excluded from the screening process. Extra measures may need to be taken to protect the privacy and confidentiality of these subjects, as well as to obtain a complete medical history. This should be taken into account when designing screening procedures for minors.

When applicable, the protocol should also specify:

- Additional precautions that are taken to remove metallic objects from the room.
- Experience that the PI and key personnel have with the MRI unit, including knowledge of or training in of safety precautions.
- Qualifications of the technicians who will perform the scan.

Tasks performed in the scanner must be described clearly.

The expected duration of the tasks/scan must be described clearly, for example:

The MRI visit will take about 2 hours, with 30 minutes allotted for screening and administrative tasks, and 1-1.5 hours for the scan and research tasks.

2. RISKS and DISCOMFORTS.

- i. Physical risks and discomforts, safety concerns.
 - a. The magnetic field of the MR environment has the potential to cause burns or bodily injury if ferrous metal objects are implanted in the body, or if personal articles containing ferrous material are brought into the environment.
 - b. The protocol must state that the risk of MRI to pregnant women and fetuses is currently unknown. See PREGNANCY, below.
 - c. Discomfort due to scanner noise. The protocol should specify that (1) this risk will be minimized by providing earplugs and/or headphones for participants and (2) the volume of the noise is not great enough to pose a health risk, with or without earplugs/headphones.
 - d. Discomfort from lying in one position for a long time. The discomfort should subside once the scan is complete, but some subjects may be sore for a more extended duration.
 - e. Peripheral nerve stimulation (PNS/tingling). At sufficient exposure levels, peripheral nerve stimulation is perceptible as “tingling” or “tapping” sensations. PNS symptoms will usually subside shortly after the scan is completed.
- ii. Psychological risks and discomforts.
 - a. Nervousness, feelings of claustrophobia. Measures to minimize this risk must be included in the protocol. Typical measures include: exclusion criterion for claustrophobia, inform participants that they may stop the scan at any time, provide participants with a handheld signaling device for communicating with investigator/technician during scanning.
 - b. Psychological risks from an incidental finding. There is a risk that the image will reveal an observation concerning an individual research participant that has potential clinical importance but is beyond the aims of the study. In the event of the confirmation of a significant anomaly in a participant’s brain image, this information will likely be distressing to the subject and constitutes a psychological risk. See INCIDENTAL FINDINGS section, below.

3. ADVERSE EVENT MANAGEMENT

The protocol should explain procedures for dealing with medical emergencies or incidents that might arise during the study. To prevent any confusion regarding the plan, it should be posted visibly in the facility.

4. PREGNANCY

The protocol must state that the risk of MRI to pregnant women and fetuses is currently unknown. Women must be informed of this fact and be given the option to complete a urine pregnancy test or dismiss the request to complete a urine pregnancy test if they believe they are not pregnant. The pregnancy test should be strongly recommended by the study staff. The protocol must specify whether female subjects who test positive are not allowed to participate in (1) the study or (2) the MRI component of the study.

If the participant wishes to dismiss the request to complete a urine pregnancy test, they must sign an agreement to acknowledge the risk and indicate that they do not believe they are currently pregnant. This is usually required immediately before the scan (e.g., in an MRI screening form).

Example:

If you are pregnant or suspect you are pregnant, you should inform the MRI technologist and/or study staff before the MRI scan. The risk of MRI to a pregnant woman or fetus is unknown. MRI is reserved for use in pregnant patients only to address very important problems or suspected abnormalities.

PREGNANCY TEST (female participants only)

Please check one:

I have taken a urine pregnancy test today and verify that the results were negative (not pregnant).

I believe that I am not pregnant and I dismiss the request to take a urine pregnancy test.

Signature: _____

Notes for protocol authors:

1. Screening tools must be attached to the submission.

5. INCIDENTAL FINDINGS

The way in which incidental findings will be handled must be described in the protocol. The pathway for evaluation of the scans should be described. Disclosure of findings of potential clinical importance should be conducted by a physician, psychologist, genetic counselor, or other professional, as appropriate. The qualifications of the person responsible for communicating an incidental finding must be described in the plan for disclosure. The expected frequency of incidental findings and clinically meaningful incidental findings should be stated.

Example:

Each image will be reviewed by the PI and/or Co-Investigators for anomalies. In the event that an anomalous brain image is identified, we will solicit the opinion of a radiologist. The cost of the consultation will be paid by study funds. If the radiologist considers the finding to be medically notable, the PI will inform the subject of the finding. The PI is a Colorado state-licensed

psychiatrist and is certified by the American Board of Psychiatry. At the request of the subject, we will provide information about the incidental finding to the subject's PCP and/or provide a specialist referral. We expect to observe at least one incidental finding in 42.9% of the scans, with 2.2% requiring further clinical action¹.

1. Orme NM, Fletcher JG, Siddiki HA, et al. Incidental Findings in Imaging Research: Evaluating Incidence, Benefit, and Burden. *Arch Intern Med.* 2010; **170**:1525-1532.

B. Informed Consent Form Example Language

The following examples should be adapted as necessary for your research study. All consent statements should be consistent with the procedures and risks described in the protocol.

1. PROCEDURES section

MRI Scan

As part of this study, you will have a magnetic resonance imaging (MRI) scan. MRI makes images of your body by using magnetic fields and radiowaves. A [*member of the research team/MRI technician*] will explain the procedure before the scan and will be present during the scan.

Before the scan starts, you will need to remove all metal objects, like jewelry, watches, and hairpins. [*If applicable, add: You may need to take off some of your clothes. If so, you will be given a gown to wear during the scan.*] You will lie on a padded table. The padded table will move into a tube-shaped magnet. The tube is only slightly larger than your body. [*If applicable, can describe enclosure: You will be enclosed in the magnet from your feet up to your waist. Or: Only your head will be enclosed in the magnet. The rest of your body will not be in the magnet.*] If you are uncomfortable in small or confined places, tell the research team.

You will have to lie very still during the scan. The magnet can be noisy. You will usually hear knocking, buzzing, and beeping sounds. We will give you [*earplugs/headphones*] to block most of the noise. You will still be able to hear us give you directions.

You will be in the scanner for about [*number of hours/minutes*]. The visit will take about [*number of hours/minutes*], because we will spend some time on paperwork and preparing for the scan.

During the scan, the MRI staff is able to see and hear you through an intercom. You will be given [*a button, a squeeze bulb, etc*]. You can use it if you need to get the staff's attention. The scan will be stopped and the staff will be able to enter the room to talk to you. You can end the scan at any time.

Notes for consent form authors:

1. When available, pictures or diagrams of the MRI procedure are useful for describing the procedure and can be added to the consent form.
2. Language in [*brackets*] must be adapted to your study.
3. Any tasks performed in the scanner must be clearly described in the PROCEDURES section of the consent form, as well.

2. RISKS and DISCOMFORTS section

MRI Scan

There are no known harmful effects from the strong magnetic field used for MRI, as long as some precautions are taken. Before the scan, you will be asked to fill out a screening form asking about anything that might be a health risk or interfere with the image.

You should not have an MRI if you:

1. Have pieces of metal in your body. The powerful magnetic field of the scanner can attract certain metallic objects known as “ferromagnetic” objects. This causes them to move suddenly and with great force. This may pose a risk to you or anyone in the way of the object. You might have metal in your body if you have:
 - a shrapnel or bullet injury
 - been a welder or metal-worker
 - non-removable metal piercings
 - tattoos on your head or neck, an older tattoo with metal-containing inks, and/or permanent makeup (eyeliner). If you have tattoos, the MRI staff will ask you about them and where they are, so they can determine whether it is safe for you to have the MRI.
2. Have certain implants and devices, because the device could move or malfunction. You should not have an MRI if you have:
 - an implanted (internal) defibrillator or pacemaker
 - cochlear (ear) implant
 - some type of clips used on brain aneurysms

You should tell the study staff if you have any other medical or electronic devices in your body, because they could interfere with the scan or could be dangerous. This includes:

- an intrauterine device (IUD)
- implanted infusion pump device like an insulin pump

- implanted nerve stimulators
- magnetic dental appliances or fillings
- metal plates, screws, staples, joint replacement, and prosthetics.

If you have another implant or device in your body, we will need to have it evaluated by [a radiologist/the PI/other qualified professional] before you can participate in the study.

3. Are pregnant. The MRI could pose risks to a pregnant woman or fetus that are currently not known. If you are a woman, we strongly recommend that you take a free pregnancy test offered to study participants. Taking a pregnancy test is your choice. If you decline this request, you will be asked to sign a document to acknowledge the risks.

Some people feel nervous or claustrophobic from the scanner's small space. If you become nervous in small, tight spaces, you should tell the study staff.

You may be sore or uncomfortable from lying in one position for a long time. The scanner can be noisy. We will give you [earplugs/headphones] to block most of the noise. The noise can be annoying, but it is not loud enough to damage your hearing. [If applicable, can add: In some experiments, you may be asked to perform tasks while you are in the scanner. Sometimes these tasks can be tiring or frustrating.]

Some people have reported sensations during the MRI scan, such as "tingling" or "twitching". This is caused by changes in the magnetic field that can stimulate nerves in your body (peripheral nerve stimulation, or PNS). The sensations will usually stop soon after the scan is completed. If you have these sensations and are uncomfortable, you can tell the MRI staff, and we will stop the scan immediately.

Incidental Findings

It is possible that we may see something in your scan that we did not expect to see. This is called an "incidental finding." In some cases, an incidental finding is important for your healthcare and requires further medical tests. This happens [add frequency, as given in protocol, e.g.: in about 2 or 3 out of every 100] research participants.

If we see something we do not expect, we will consult with a [radiologist/other healthcare professional]. You will not be charged for the consultation. If the [radiologist/other healthcare professional] decides that the incidental finding could be important for your healthcare, we will tell you about it. We can give information about the incidental finding to your primary doctor and/or refer you to a specialist. We will only tell you about the incidental finding if the [radiologist/other healthcare professional] decides that it could be important for your healthcare. If it is not found to be important for your healthcare, we will not tell you about it.

An incidental finding may make you feel anxious. If you have further tests done, those results will then become part of your medical record. This may affect current and future health or life insurance. There are no plans to pay for the costs of any care that will be needed to diagnose or treat you. Those costs would be your responsibility.

This study is neither designed nor intended to find health problems. The scan that you will have does not substitute for an appropriate medical exam by a qualified healthcare provider. If you think that you might be suffering from injury or illness, you should not rely on this research study as a way to determine your health status.

Notes for consent form authors:

1. Language in [*brackets*] must be adapted to your study.
2. Risks and discomforts resulting from the tasks performed in the scanner must be clearly described in the RISKS and DISCOMFORTS section of the consent form, in addition to the example language provided above.