MRI Standard Language for Consent Forms

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Background:

MRI and fMRI are considered “minimal risk” by the FDA, and thus by the IRB. However, all research studies involving an MRI for research purposes should contain template language with the informed consent to explain the MRI to the subject.

There is a separate guidance entitled “Incidental Findings” [provide link] to insert template language if deemed appropriate.

Q: What is the standard language that the IRB wants me to use?

If you WILL use sedation in order for the subject to get the MRI but will not be enrolling women of childbearing potential:

Magnetic resonance imaging (MRI) is a procedure that allows doctors to look inside the body by using a scanner that sends out a strong magnetic field and radio waves. This procedure is used routinely for medical care and is very safe for most people, but you will be monitored during the entire MRI scan in case any problems occur. The risks of MRI are:

- The MRI scanner contains a very strong magnet. Therefore, you may not be able to have the MRI if you have any type of metal implanted in your body, for example, any pacing device (such as a heart pacer), any metal in your eyes, or certain types of heart valves or brain aneurysm clips. Someone will ask you questions about this before you have the MRI.

- There is not much room inside the MRI scanner. You may be uncomfortable if you do not like to be in close spaces (“claustrophobia”). During the procedure, you will be able to talk with the MRI staff through a speaker system, and, in the event of an emergency, you can tell them to stop the scan. If have claustrophobia, you may require medication to help you relax (“sedation”). If you do require medication to relax, you should not drive a car, take part in activities like riding a bike, or perform other similar tasks until the next morning because the medication(s) can affect your thinking for several hours and can slow down your reflexes.

- The MRI scanner produces a loud hammering noise, which has produced hearing loss in a very small number of patients. You will be given earplugs to reduce this risk.

Q: What if women of childbearing potential are included, but will NOT be using sedation?

The following language should be included:

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• The MRI scanner produces a loud hammering noise, which has produced hearing loss in a very small number of patients. You will be given earplugs to reduce this risk.

• If you are a woman of childbearing potential, there may be unknown risks to the fetus. Therefore, before you can have the MRI, you must have a pregnancy test.

Q: What if women of childbearing potential will be included and sedations will be used?

The following language should be used:

Magnetic resonance imaging (MRI) is a procedure that allows doctors to look inside the body by using a scanner that sends out a strong magnetic field and radio waves. This procedure is used routinely for medical care and is very safe for most people, but you will be monitored during the entire MRI scan in case any problems occur. The risks of MRI are:

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• If you are a woman of childbearing potential, there may be unknown risks to the fetus. Therefore, before you can have the MRI, you must have a pregnancy test.

Q: What if I will not be using sedation or enrolling women of childbearing potential?
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• The MRI scanner produces a loud hammering noise, which has produced hearing loss in a very small number of patients. You will be given earplugs to reduce this risk.