



BROWN

Human Research Protections Office

**BROWN UNIVERSITY  
MRI RESEARCH FACILITY  
INFORMED CONSENT ADDENDUM**

**RISKS AND DISCOMFORTS**

Magnetic Resonance Imaging (MRI) uses a powerful magnet to take pictures of your body. Because the MRI machine exposes the body to a very strong magnetic force, you will have to follow certain safety precautions to make sure you do not have any metal objects in, or on, your body. Before you undergo your MRI scan, a researcher or technician will ask whether or not your body contains any metallic medical devices or equipment, including heart pacemakers, metal prostheses, implants or surgical clips. You also will be asked whether you have had any prior injury from shrapnel or grinding metal, and you will be asked whether your eyes have been exposed to metallic dust or metallic shavings. You, or the researcher or technician, will also complete a checklist that addresses issues of MRI safety.

If you have no metallic objects or particles in your body, you will be asked before entering the MRI room to remove from your person all metal objects, including jewelry, watches, hair holders, or eyeglasses; and you will be asked to empty your pockets of all materials, including keys, wallets, and magnetic cards such as ATM and credit cards. In addition, if your clothing has more than a minimal amount of metal content, you may be asked to change into a hospital gown or other suitable garment. Finally, you will be asked to remove any eye shadow you may be wearing, because eye shadow sometimes contains metallic substances.

After you enter the MRI room, you will be asked to lie on your back on a table that slides into a horizontal cylinder slightly wider than your body. Because the MRI machine makes loud noises while it scans, a researcher or technician will provide you with ear protection to reduce the noise level. When you and the researcher or technician are ready to begin the MRI scan, you will be asked to lie as still as you can.

MR imaging is generally considered to be safe; but accidents, injuries, and even deaths have occurred during MRI procedures. Such adverse events are extremely rare if appropriate safety precautions are followed. Serious complications can occur in people who have metal pacemakers, metallic dust in the eyes, or certain types of metal prostheses, implants, or surgical clips. MRI is also dangerous for anyone wearing any metal objects, including jewelry, watches, hair holders, eyeglasses or metal on clothing, as well as eye shadow, which sometimes contains metallic substances. In addition, if you enter the MRI room with any magnetic cards, such as ATM and credit cards, you will risk having the data on the cards erased by the MRI machine. For these

reasons, a researcher or technician will review safety information with you before the scan. In order to determine whether it is safe for you to undergo the scanning procedure, it will be important that you tell the technician about any metallic objects or devices in, or on, your body.

During the scan itself, you will lie on a table that slides into a horizontal cylinder slightly wider than your body. You will be asked to lie still, but you will be able to hear and speak to the MRI personnel/research staff. Some people experience anxiety, panic, or a sensation of claustrophobia when lying in the MRI machine. If you think this may happen to you, please tell the researchers before you have the scan. The scanner also makes loud noises during imaging. Ear protection will be provided to reduce the noise level. If you feel uncomfortable for any reason before or during the procedure, please tell the researchers. If for any reason during the procedure you want to stop, you may do so at any time.

There is a risk of heating from radiofrequency imaging coils, the cables of radiofrequency imaging coils, and/or the cables from monitoring devices such as those that record physiologic processes by way of an electrocardiogram, pulse oximeter, and/or plethysmograph. Please report any heating/burning sensation immediately. You are encouraged to signal to have the scan stopped at any time if this occurs.

The MRI scanner used for this study has been approved for clinical use by the FDA. However, this scanner will be operated in "research" mode for this study, in which case the scanner is considered by the FDA to be an "Investigational Device." Also, some of the radiofrequency imaging coils and/or the imaging software being used to perform scans at the Brown University MRI Research Facility are not approved by the FDA. Nevertheless, there are no known significant risks with this procedure at this time since the radiofrequency magnetic fields and magnetic fields, at the strengths used, are felt to be without harm. There are conservative Federal guidelines for radiofrequency magnetic field exposure and our examinations fall within those guidelines. We feel these are safe levels and less hazardous than a comparable x-ray computer tomography examination.

**FOR WOMEN:** The safety of MR imaging during pregnancy has not been proved. If you are, or might be, pregnant, you cannot take part in this study.

**CAUTION:** This study is neither designed nor intended to detect health problems in participants. The MRI scans that you will undergo do **not** substitute for an appropriate medical examination by a qualified health care provider. If you suspect that you might be suffering from injury or illness, including any injury involving the head or brain, you should **not** rely on this study as a way to determine whether or not you are well.

The investigators for this project are not trained to perform radiological diagnosis, and the MRI scans performed in this study are not designed to find abnormalities. The investigators and Brown University are not responsible for failure to find existing abnormalities in your MRI scans. However, on occasion the investigator may notice an MRI image that seems abnormal. When this occurs, the investigator will inform

you and recommend that you consult with your primary care physician. The decision whether to proceed with further examination or treatment lies solely with you and your physician. The investigators and Brown University are not responsible for any examination or treatment that you undertake based upon these findings. Because the images collected in this study do not comprise a proper clinical MRI study, these images will not be made available for diagnostic purposes.

#### COMPENSATION IN CASE OF INJURY

Many forms of research involve some risk of injury. In spite of all the care and precautions taken by the investigators, you might develop medical complications from participating in this study. If such complications arise, the researchers will, upon your request, provide information that may be of assistance to you in obtaining appropriate medical treatment. Brown University does not provide financial assistance for medical or other costs. Additionally, Brown University is not responsible for research and medical care by other institutions or personnel participating in this study. You do not waive any liability rights for personal injury by signing this form.

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Participant Signature