PARTICIPATION IN AN IMAGE QUALITY ASSURANCE PROCESS

Healthy Volunteer for Image Quality Assessment

Name of Participant: ________________________________

You are being asked to participate in an image protocol development process or an image quality assessment process through which the quality of the images produced by our magnetic resonance imaging (MRI) equipment is being assessed. The purpose or aim of this evaluation is not to diagnose any disease or condition you may or may not have. A member of the imaging team will explain what is involved in this process and how it will affect you.

WHY IS THIS EVALUATION BEING PERFORMED?

The purpose of this evaluation is to improve the quality of the images produced by an MRI scanner. As part of this process, you are being asked to undergo an MRI scan to verify the quality of the images produced by the MRI equipment. This form describes the MRI scan as well as the risks associated with this type of scan. Your participation will be limited to this single MR scan.

WHAT IS INVOLVED IN THE EVALUATION?

MRI is a non-invasive imaging technique. The advantages of MRI include excellent demonstration of soft tissues, which can be displayed in various ways without exposure to ionizing radiation.

MRI images are produced by using pulsed radio waves and changing magnetic fields to temporarily manipulate the magnetic parts of the atoms that make up your body. Millions of MRI scans have been performed at numerous locations around the world. In many cases, the resulting images show important medical information that could not be obtained in any other way. The timing and strength of the radio waves and magnetic field pulses produced by the MRI scanner affect the information that is contained in (and the quality of) the resulting images. The purpose of this evaluation is to understand exactly how these timing factors influence the appearance of the resulting images and our ability to understand normal anatomy and/or function and to learn how anatomy and/or function are affected by disease.

If you agree to participate, you will first be asked a number of questions to make sure it is safe for you to participate. For instance, you will be asked whether you have any metal in your body, such as a pacemaker or a metal surgical plate. Once it is determined that it is safe for you to participate, you will be brought to the MRI scanner. During the scan, you will be in the long tubular opening of the scanner, and you will hear loud “knocking” or “drumming” noises. You may be provided with sound-canceling headphones that reduce the noise level. A skilled MRI technologist will be present at all times: before, during, and after the scan. The MR technologist will have access to emergency support in case of an unexpected difficulty or health concern.

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You will be able to speak to the MRI technologist throughout the scan. If you become uncomfortable at any time during the scan, you may stop the scan and be removed from the scanner by simply telling the technologist.

The scans will be reviewed by a team of experts that may include practicing physicians. The sole purpose of their review, however, will be to determine whether the quality of the acquired images is adequate. The reviewers will not be looking at your scan in order to diagnose any condition you may or may not have, and they will not have access to your medical history as part of their review. You may be contacted by imaging personnel in the unlikely event that a potentially clinically relevant finding happens to be observed incidentally by the reviewers, although, again, the reviewers will not be looking at your scans in order to diagnose any condition you may or may not have.

These scans are not intended to diagnose any disease or condition you may have and will not be so interpreted.

A copy of this scan will NOT be included in your medical record and will NOT be made available to you.

WHAT ARE THE RISKS OF THIS EVALUATION?
Strong magnetic fields may loosen metallic implants, causing bleeding and tissue damage; these fields may also cause abnormal function of electrical pacemakers and stimulators. Also, radio waves may heat the body and metallic objects within or on the body, possibly resulting in burns. Therefore, you should not participate if you have metallic implants, electrical pacemakers, or electrical stimulators. Furthermore, you should not participate if you have had a previous accident or occupational exposure that could have resulted in metal fragments lodged in your body. All metal jewelry and accessories should be removed prior to the scan.

Iron objects may fly into the scanner and strike you if they are attracted by the magnetic field of the device.

You may become anxious about being confined in the small tubular opening of the scanner, and you may want to get out of it. If this occurs, the scanner has a “call button” that you may activate at any time during the scan to end the scan.

The MRI equipment that we use includes all of the safety features provided by the manufacturer. Experience at the University of Chicago and many other sites worldwide has shown the instrument to be safe for routine use.

WHAT ABOUT CONFIDENTIALITY?
Faculty at the University of Chicago Medical Center may electronically submit anonymized copies of your scan to outside entities as part of the image quality assurance process. The anonymized images may also be used for teaching purposes.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
You have talked to _________________ about this evaluation, and you had the opportunity to
ask questions concerning any and all aspects of the evaluation. If you have further questions, you may call ____________.

The image protocol development process or image quality assessment process and the procedures associated with it have been explained to me.

I agree to participate in this evaluation. My participation is voluntary and I do not have to sign this form if I do not want to be part of this evaluation.

Signature of Participant: ________________________________
Date: ____________       Time: _____ AM/PM (Circle)

Witness: ________________________________
Date: ____________       Time: _____ AM/PM (Circle)
Department of Radiology
Employee MR Safety Screening Form

Name_____________________________Department_________________Badge Number________________

Do you have any of the following items in or on your body?

☐ Yes ☐ No  Aneurysm clip or coil
☐ Yes ☐ No  Cardiac Pacemaker, pacer wires, or implanted cardioverter defibrillator (ICD)
☐ Yes ☐ No  Neurostimulators (brain, spine, bone, etc.)
☐ Yes ☐ No  Internal electrodes or wires
☐ Yes ☐ No  Eye or ear implant, springs or wires (e.g. cochlear implant)
☐ Yes ☐ No  Tissue expanders (e.g. breast)
☐ Yes ☐ No  Metallic stent, filter, coil or heart valve  Please specify type and location:__________________________
☐ Yes ☐ No  Magnetically activated implant or programmable device (e.g. VP shunt)
☐ Yes ☐ No  Shunt (spinal, brain or intraventricular)
☐ Yes ☐ No  Insulin or other infusion pump  If Yes, please indicate if internal or external__________________________
☐ Yes ☐ No  Joint replacement or any type of prosthesis (eye, hip, knee, etc.)
☐ Yes ☐ No  Bone or joint pin, screw, nail, wire, plate, etc.
☐ Yes ☐ No  Hearing aid
☐ Yes ☐ No  Swan Ganz Catheter
☐ Yes ☐ No  Surgical staples, clips, or metallic sutures
☐ Yes ☐ No  Dental or partial dental plates
☐ Yes ☐ No  Medication patch (Nicotine, Fentanyl, Nitroglycerine)
☐ Yes ☐ No  Penile implant or pump
☐ Yes ☐ No  Body piercing or tattoos
☐ Yes ☐ No  Any metallic fragment or foreign body
☐ Yes ☐ No  Have you had an injury to the eye involving a metallic object or fragment?
☐ Yes ☐ No  Have you ever been injured by a metallic object (bullet, shrapnel, etc.)?
☐ Yes ☐ No  Do you have any breathing problems or claustrophobia?

For Female Employees:

☐ Yes ☐ No  Are you pregnant or suspect that you might be?
☐ Yes ☐ No  Are you breast-feeding?
☐ Yes ☐ No  Do you have an IUD?

Comments:_________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________

Employee Name (Print)_________________________Employee Name (Sign)_________________________Date/Time_________________________

Reviewed By Name (Print)_________________________Reviewed By Name (Sign)_________________________Date/Time_________________________