RE: Guidelines for Use of Consent and Waiver of Liability Form for Non-Clinical, Non-Research, MR Exams.

From: Scott B. Reeder, MD, PhD; Frank R. Korosec, PhD; Howard A. Rowley, MD
Department of Radiology, University of Wisconsin-Madison

Magnetic resonance imaging (MRI) is performed primarily in patients for clinical purposes, or for imaging human subjects recruited for research projects that are institutional review board (IRB) approved.

If an MRI study is performed for clinical purposes, a physician order is required. If the activity constitutes research, an approved IRB protocol is necessary. Research is defined as "a systematic investigation, designed to develop or contribute to generalizable knowledge", according to the federal government. However, there are other appropriate situations that use MRI in humans (hereafter "volunteers") that constitute neither research nor clinical MRI. The purpose of this document is to provide guidelines for the use of MRI at UW-Madison in volunteers that is not performed for clinical or research purposes. At UW-Madison, the use of MRI for non-research, non-clinical purposes may be performed, without IRB approval, under certain circumstances, including, but not limited to the following:

1. **Clinical Protocol Development:** When developing new clinical MRI protocols or refining established clinical protocols it is appropriate to image volunteers in order to ensure adequate image quality has been achieved prior to using these protocols in patients for clinical purposes.
2. **Training and Teaching:** It is appropriate to scan volunteers for the purposes of teaching students and for training operators on the safe and effective use of MRI systems. All teaching and training should be performed under the direct supervision of an experienced MRI operator.
3. **Quality Assurance Testing:** Testing of existing or new equipment often requires testing in volunteers to evaluate system performance. Evaluation may include (but is not limited to) testing of signal-to-noise ratio (SNR) performance, evaluation of image artifacts, and any metric related to the performance of the MRI system.

The following principles and requirements apply for scanning volunteers for non-clinical/non-research purposes:

1. Minimize the use of volunteers for these purposes, and use phantom scanning where possible.
2. Should there be any doubt regarding whether an activity involving non-clinical MRI represents research or not, communication with Gemma Gliori, the Department of Radiology regulatory specialist, is encouraged.
3. All scanning under this policy will be performed in adults only (18 years and older).
4. All volunteers must be screened using a standard MRI Safety Screening form. If there is uncertainty regarding a potential contraindication, the volunteer should not go in the MRI suite. Volunteers who are, or may be pregnant will not undergo MRI for these purposes. All screening forms must be reviewed and approved by trained personnel such as an MR technologist, MR nurse, or radiologist, prior to the volunteer entering the MRI suite.
5. A new safety screening form must be completed each time a volunteer is scanned, unless he/she is scanned more than once on the same day.
6. Informed consent must be obtained and witnessed every time a volunteer is scanned, using the non-clinical/non-research consent form that was developed specifically for this purpose. A new consent form must be completed each time a volunteer is scanned, unless he/she is scanned more than once on the same day.
7. With informed consent, FDA-approved contrast agents may be administered at standard clinical doses. It is recognized that the administration of contrast agents may be necessary for clinical protocol development, training and teaching purposes. In general, the use of contrast agents should be minimized for these purposes, and limited for each volunteer to no more than one contrast administration every 3 months.
8. Only approved personnel who have CITI training are permitted to obtain consent from volunteers.
9. Sites eligible to use the non-clinical, non-research consent form include the University of Wisconsin Hospital and Clinics (UWHC), the American Family Children's Hospital (AFCH), the Wisconsin Institutes for Medical Research (WIMR), the Waisman Center, the Health Emotions Research Institute (HERI), the 1 S. Park Street Clinic, The American Center (TAC), or the UW Sports Medicine Clinic at Research Park.

Questions: Please contact Scott Reeder (pager 6713, sreeder@wisc.edu), Vinny Meduri (pager 4110, VMeduri@uwhealth.org), or Andy Alexander (alalexander2@wisc.edu).