

Safety Guidelines for Conducting Magnetic Resonance Imaging (MRI) Experiments Involving Human Subjects

UCSD Center for Functional MRI, April 4, 2008

NOTE: *These safety guidelines supplement and update the main safety guidelines from July 2007. Guidelines 1 through 6 apply to **all** subjects and studies.*

- 1) For **all** subjects and studies, a safety-certified adult should continuously monitor the subject's status throughout the scan session. If a monitor (see guidelines 6 and 9 below) is not present in the magnet room, the window blinds should be open for visual monitoring, and the intercom should be set at a level that is sufficient to hear the subject. In addition, the subject should be given the squeeze bulb and trained in its usage. To minimize unnecessary squeezing of the bulb, the squeeze bulb can be taped to the subject's thigh.
- 2) We expect to install an MRI-compatible video monitoring system within each magnet room later this year (2008). Once this system is installed, the use of the system is strongly recommended for all studies. The use of a pulse oximeter is also strongly recommended – this provides an additional mechanism for monitoring the subject's status.
- 3) The use of a mock scanner is strongly encouraged. We expect to install a mock scanner at the Center later this year (2008). In addition to training related to study procedures, the subject should also be trained on safety and communication issues (e.g. how to use the squeeze ball, how to talk with the operator, how to signal the operator if there is a problem).
- 4) Staff members from the Center will occasionally audit scan sessions to verify compliance with the Center's safety policies. Unscheduled usage of the scanner poses a safety risk, especially after hours. Scanner usage will be audited to ensure that usage of the scanner complies with the webschedule and that proper screening forms are submitted with each scan.
- 5) In the event of an emergency, a Center staff member should be contacted immediately for assistance. If a staff member is not available, then the operator should contact the numbers listed on the **Emergency Call List** posted in each console room.

Guidelines 6 through 8 apply to subjects under the age of 13, while Guideline 9 applies to subjects (13 years and older) who may require additional monitoring.

- 6) For children under the age of 9, an adult monitor must remain in the magnet room with the child throughout scanning. In addition, an adult monitor must remain in the magnet room with any child (under 13 years) that exhibits anxiety or requests accompaniment. As part of routine procedure, the operator should ask the child if they would prefer to be accompanied in the scanner. Furthermore, if there is any doubt about the child's ability to follow safety instructions while in the magnet room, an adult monitor must remain in the magnet room. The adult monitor must be (i) a certified operator, (ii) a research assistant who is safety certified, or (iii) a parent or legal guardian who has undergone safety screening and been instructed in the use of the safety squeeze bulb. The adult monitor should have a squeeze bulb to notify the operator if there is a problem. Finally, the adult monitor must wear both earplugs **and** protective earmuffs while in the magnet room.
- 7) For imaging sessions involving subjects under the age of 13, there should be at least two safety-certified adults at each scan session. **One** adult is the operator. The **second** adult should be either an operator or a safety-certified researcher (faculty/staff/student) who can assist in monitoring of the subject. If there are additional children (e.g. siblings) present during the scan session, a **third** adult should be available to monitor their activities, ensure their safety, and ensure that others working at the Center are not disturbed.
- 8) All researchers who are involved with pediatric scanning are required to attend an additional training session focused on the issues particular to the scanning of children. This will include issues of assent and consent, techniques for increasing compliance in children, testing limits for children, use of a mock scanner, how to deal with anxious subjects, how to determine if an older child needs someone in the room, etc. Attendance at additional refresher training sessions may also be required as the safety policies evolve.
- 9) For subjects (13 years and older) who exhibit diminished cognitive capacity and may not be able to follow safety instructions while in the magnet room, an adult monitor must remain in the magnet room with the subject throughout scanning. The monitor must be (i) a certified operator, (ii) a research assistant who is safety certified, or (iii) a parent, legal guardian, or legally authorized representative who has undergone safety screening and been instructed in the use of the safety squeeze bulb. The monitor should have a squeeze bulb to notify the operator if there is a problem. Finally, the monitor must wear both earplugs **and** protective earmuffs while in the magnet room.