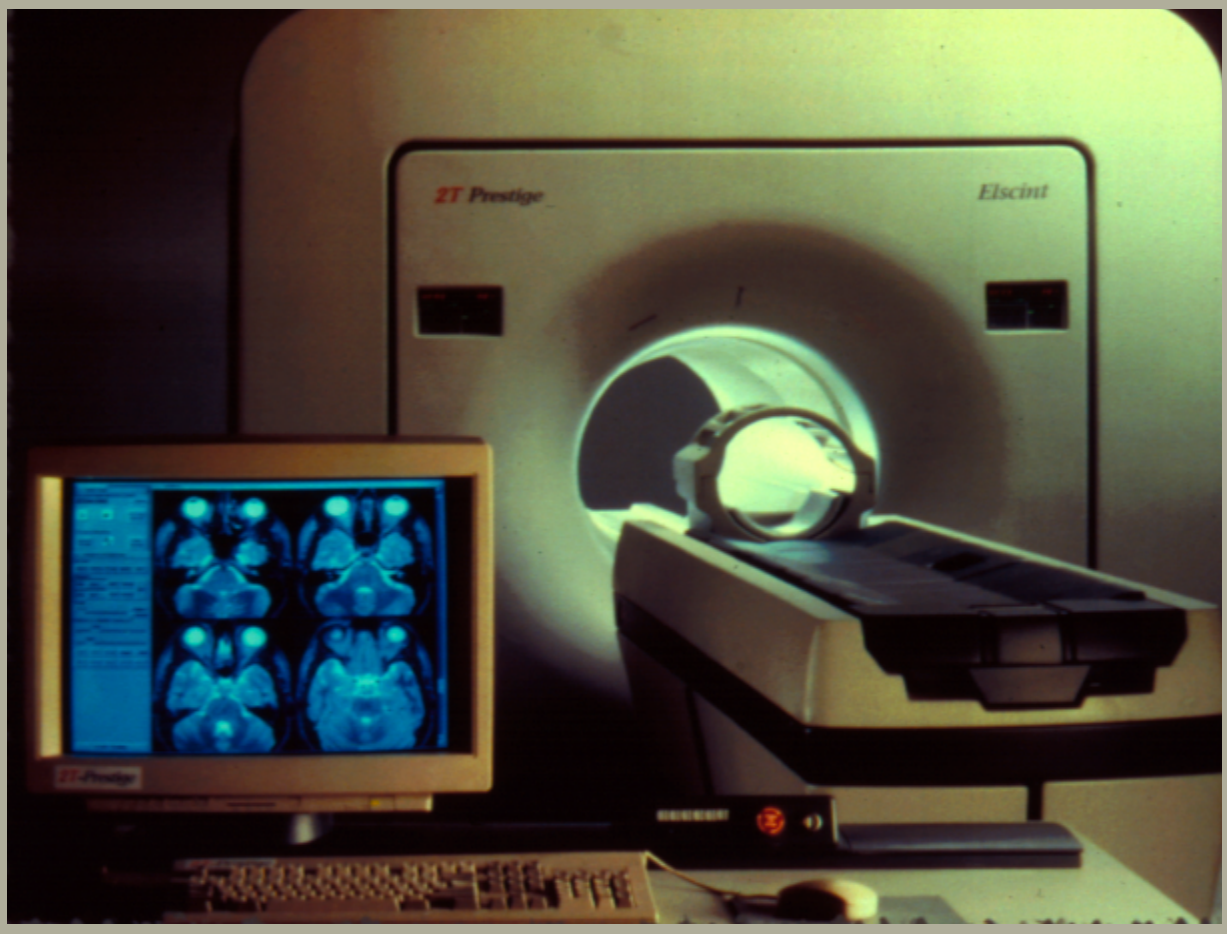
# MRI Research Safety and Ethics




# Points to Consider

NIMH Council Workgroup on MRI Research Practices

# MRI Research Safety and Ethics: Points to Consider

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**Sponsored by:**
**NIMH Council Workgroup on MRI Research Practices**

**Summary**

## Background and Purpose

As with any complex and evolving technology, the use of magnetic resonance imaging (MRI) for research raises important issues concerning the protection of human subjects or participants. In view of the increasing involvement of MRI technology in human subjects (HS) research, particularly in non-clinical (i. e., university rather than mainly medical research) settings, NIMH recognizes the need to consider safety and ethical issues related to both the administration of MR (magnetic resonance) facilities and the use of these facilities for research.

What was once a tool used primarily for medical diagnosis has become a valuable tool for clinical and basic cognitive and affective neuroscience research. This evolution raises questions regarding how to protect the safety of participants without unduly impeding important research. Although the protection of human participants must remain the paramount consideration, regardless of the setting in which MRI research occurs (e.g., university settings vs. medical centers), approaches to and use of MRI in research vary by context or environment. NIMH recognizes the lack across various research settings of any comprehensive guidance to assist investigators in reviewing the issues posed by MRI research concerning the safety and protection of human participants.

To address the above-noted concerns, the National Advisory Mental Health Council (NAMHC) Workgroup on MRI Research Practices was convened on September 14, 2005. Participants included NIMH Council members engaged in MRI research, intramural and extramural scientists including those involved in pediatric work, MR safety experts, including MR physiologists, MR physicists and neuroradiologists, and an attorney with expertise in health-related research issues. The major goal of the Workgroup was to enhance the protection of human participants by developing a set of "points to consider" for institutions and investigators conducting or considering MRI research. The NIMH believes that investigators, institutions and facilities can use this document as a resource for the development, administration, evaluation, and use of MRI research facilities.

The development of this document was guided by peer-reviewed publications and empirical data to the fullest extent possible. Where sufficient data were lacking, the Workgroup sought to acknowledge this

limitation and to identify the need for additional data. Furthermore, because technology is evolving rapidly and new applications of MR continue to be discovered, it is expected that new questions will arise. Thus, this list should be updated periodically if it is to be kept current.

Many of the issues discussed here have been considered previously in some form in the American College of Radiology (ACR) White Paper on MR Safety, published in 2002 and revised in 2004 (Kanal et al., 2002, 2004) and in other recent publications (Shellock, 2001, 2006; Shellock and Crues, 2004). Researchers are strongly encouraged to consult these documents, and wherever relevant and appropriate, to follow the recommendations contained therein. The ACR reports were focused primarily, however, on the use of MR in medical settings. The present considerations are intended to encompass the broader use of MRI in human neuroscience research, including studies conducted at facilities that exist outside of medical settings. These research settings raise additional issues that are complementary to those addressed by the ACR report. Consideration of these research-specific issues was a primary focus of the NIMH Council Workgroup.

This document summarizes the "points to consider" discussed by the NAMHC Workgroup. Examples of safe and ethical practices are discussed in relation to several issues. These examples are intended to be illustrative and should not be interpreted as an exhaustive or exclusive list. This document was presented to the full NIMH Council on September 15, 2006 and approved unanimously. By making the "points to consider" document available publicly, NIMH intends to provide a resource for researchers and institutions that use MRI in research.

## Organization of Meeting and Report

The agenda was organized into six topics, which provide the organization for the points to consider that follow:

A. MRI screening
B. Training, operating, and emergency procedures
C. Physical facilities
D. Scanning/participant health variables
E. Context- Specific Considerations: University vs. medical settings
F. Additional data needs and updating

## Points to Consider

### A. MRI Screening

**Are there procedures in place to ensure the adequate screening of participants prior to scanning?**

**A-1. Is a screening form designed for maintaining MR safety in use at the facility as part of the research?**

The Workgroup agreed on the need for careful and comprehensive screening of all individuals who enter the MRI suite, i.e., all participants and any caretakers, such as parents, who accompany children into the MRI suite, as well as anyone who routinely enters or has access to the facility (e.g., maintenance workers, security, as well as cleaning and emergency personnel). The use of a screening form was felt to constitute a useful approach. The Workgroup felt that it was good practice to document all screening procedures in writing and to make this information available to MRI facility researchers and staff.

A sample screening form is included in the American College of Radiology White Paper on MR Safety, along with the accompanying MR Safe Practice Guidelines (Kanal et al., 2002). Another sample screening form for patients and research subjects may be downloaded from www.mrisafety.com or www.IMRSER.org. A Spanish version of this screening form is available from the ACR website: www.acr.org.

**A-2. Are there concerns about the participant's comprehension of questions related to issues of safety?**

The Workgroup recognized the need for complete and trustworthy information from participants and/or their caregivers and was concerned that incomplete or inaccurate responses to the items included on the screening form would be problematic. The participant should comprehend the questions on the screening form and sign an informed consent form. In situations where there are questions or concerns about the participant's comprehension (due to factors such as questionable decision-making capacity, etc.), but the participant is nevertheless considered able to provide informed consent, the Workgroup recognized the value of having a knowledgeable companion, caretaker or family member present, with the consent of the participant, for the consent process. If there is a language barrier, an interpreter who is not a member of the participant's family is recommended. Also appropriate in specific circumstances is the participation of an independent physician, consent monitor, or other responsible party to help determine that the participant satisfies all criteria for MR safety clearance prior to entering the MRI suite. Clearly the responsibility for ensuring that it is safe for the participant and/or accompanying family/other members to enter areas in the MRI environment that pose risks due to the presence of the magnetic field (described below as "zones 3 or 4", see Section C-1) rests solely with the Principal Investigator and research facility.

**A-3. Once the participant completes the screening form, is the information reviewed in a screening interview?**

The Workgroup recognized the value of having the screening form for the participant and/or any caretaker who might accompany the participant into the scanner suite reviewed by a qualified interviewer who has the authority or access to the authority to deny entry into the MRI suite and to decline to scan. The following credentials were considered by the Workgroup as qualifying the screening interviewer for this role: (a) Defined training and experience in MR safety and an understanding of the potential hazards involved in both the MR environment and the MR imaging process; (b) knowledge of medical and dental devices and implants and of foreign metallic materials and conditions that pose hazards to the health and safety of individuals in the MR environment; and, (c) knowledge of how to assess the MR safety aspects of implants and medical and dental devices and foreign metallic materials or how to access appropriate

and authoritative information. (See also B-1 concerning training.)

The Workgroup also recognized the value of having the interviewer administer and review the screening form with the participant item by item, to satisfy himself/herself that the participant has thoughtfully considered each item and that there are no contraindications to scanning. This procedure would provide greater protection than relying solely on the participant independently filling out a written screening form. Similarly, having the interviewer sign and date the screening form was recognized as adding value.

The importance of the interviewer's access to appropriate resources for resolving any questions related to the safety of questionable implants, medical or dental devices or foreign metals or objects was acknowledged. Avenues for checking the safety of devices are numerous, and include, first, written contact with the manufacturer of the device, peer-reviewed published information, web searches and/or consultation with designated safety experts, and discussion with an MR physicist or MR-trained radiologist, among others.

The Workgroup also recognized that, within the research context, MR safety information may be less available for higher field strengths (e.g., 3 Tesla (T)) and that the safety aspects of devices may vary depending on how they are used. Thus, ready access to an identified individual with the expertise to evaluate safety in specific situations is invaluable.

In summary, the Workgroup recognized the value of a qualified interviewer taking responsibility for ensuring that the screening has been completed, that the screening is documented in writing with the interviewer's signature and date, and that any questionable devices are considered safe based on the consultation of an appropriate expert source.

**A-4. Have potential contraindications to scanning been identified?**

The Workgroup agreed that if the screening yields information that raises a question concerning safety, steps should be taken to resolve the question prior to proceeding. An example would be a metalworker who vaguely recalls an accident in which metal filings may have entered an injured the eye. In this situation, screening, e.g., orbital film, should be used to rule out this contraindication to scanning. Institutional Review Board (IRB) permission to acquire screening studies involving ionizing radiation needs to be prospectively obtained. If this type of follow-up screening is not definitive or unavailable (e. g., due to cost), the safest action would be to exclude the participant.

If information indicates a foreign body is present, the Workgroup recognized the importance of determining its MR safety prior to scanning.

**A-5. Do the screening procedures provide for redundancy?**

The Workgroup recognized that a second approach to screening would provide redundancy and therefore might increase safety. This second approach might involve a second interview just prior to scanning to decrease the probability of missing an item that might pose a threat to safety.

As an alternative to two full interviews, a researcher could choose to include MR contraindications as part of the screening for recruitment to the study. This brief interview could be performed prior to a participant coming in for testing. This pre-screening should supplement, but not replace, the full MR screening interview. On the day of testing, a qualified interviewer at the MR center would provide a thorough in-person screening interview.

Another alternative is the use of a second approach to ensure that the participant is free of surface objects that may be unsafe for MRI (such as pens, coins, other metals). For example, this may consist of having a child turn all his/her pockets inside out to ensure that they are empty or a check of all pockets and the body using an appropriately sensitive ferromagnetic-detector wand (see Section A-6 below). As a third alternative, participants could be required to remove all clothes and jewelry and wear a gown. It remains the responsibility of the principal investigator and the research facility to ensure to the best of their ability that the participant does not have any ferromagnetic or other potential contraindicated devices/items within them as a result of prior trauma, surgery, etc.

**A-6. Is a hand-held high-strength magnet available for screening purposes?**

The Workgroup also recognized the value of having a high strength magnet (1000 gauss or more) available for possible use as a supplement to screening, but recognized that its use should not replace the screening interview. Whereas such a device might be useful for assessing the ferromagnetic status of, and screening out, potentially dangerous objects, it would not ensure that objects are safe in the MR environment (false negatives). Thus, the Workgroup expressed a need to recognize that the use of this magnet was supplementary to a thorough screening process and not meant in any way to replace it.

**A-7. What role do ferromagnetic detectors play in the screening process?**

Ferromagnetic detectors include hand held, wall-mounted and walk-through models designed to sound an alarm when ferrous objects are detected, but to allow ferrous free, metallic objects through. Sufficiently sensitive ferromagnetic detectors have the potential to reduce the risk of projectile incidents, patient injury and damage to equipment. However, such devices have not yet been systematically tested with respect to this potential. Therefore, the Workgroup opined that, at this time, ferromagnetic detectors cannot replace a conscientious screening and/or direct physical inspection, but constitute a potentially useful supplement to other screening measures.

**A-8. What steps are in place to screen for pregnancy?**

At present, there is no known risk of MR brain scanning of a pregnant woman to the developing fetus for scanning at 4T or less, and no known mechanism of potential risk under normal operating procedures. Nonetheless, the possibility that risks may be discovered in the future cannot be ruled out. Therefore, exposure of fetuses to MR scanning without any prospect of direct benefit may not be ethically justifiable. Indeed, the general policy in many clinical Radiology Departments is not to scan anyone who may be pregnant, absent compelling clinical need. Thus, it is appropriate to screen for pregnancy and to exclude

pregnant participants for the sake of caution.

A somewhat separate, but related, issue is the fact that there may be potential risks associated with the exposure of fetuses to some intravenously administered MR contrast agents.

It appears that most local IRBs intend to exclude potential participants who are pregnant from research MRI procedures. Based on Federal HS protection regulations (see below), the Workgroup expects that pregnant females will not knowingly be scanned for research purposes unless the pregnant mother and/or fetus are the subject of an IRB approved protocol that specifically provides for the inclusion of pregnant women and fetuses in the research. Such research would need to utilize appropriate informed consent procedures consistent with the requirements of the Code of Federal Regulations (CFR) Title 45 (Public Welfare) Part 46 (Protection of Human Subjects), Subpart B (Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research) (45 CFR Part 46, Subpart B), as applicable.

A variety of approaches are used across centers to screen for and/or exclude pregnant or possibly pregnant participants. Some sites simply note, during the consent/assent process, that the individual should not participate if there is a possibility she may be pregnant. Other sites use questions that include the date of the last menstrual period and/or whether there is any chance the potential participant might be pregnant. Still others test for pregnancy in all females who have begun menstruation unless they are post-menopausal or have undergone surgical procedures after which pregnancy is not a possibility. The approach which will be used to screen for pregnancy should be described in the protocol in order for the IRB to assess the risks and benefits of the protocol.

Pregnancy testing has the benefit of providing new information in cases where a female may not yet realize she has conceived. Without such testing, a female may be scanned while unknowingly pregnant. At the same time, pregnancy testing holds implications for the disclosure of such results. For example, having a parent first learn of a child's sexual activity and/or pregnancy during the consent/assent or screening process may be harmful for the adolescent female and her family; sensitivity to cultural influences is warranted here. Caution is warranted to avoid accidental disclosures of pregnancy to individuals who might be accompanying the participant.

If disclosing a pregnancy can have potential negative consequences/risks under certain circumstances, IRBs will want to consider this issue. Investigators should consider, in advance, how an "incidental finding" of pregnancy will be managed, i.e., whether appropriate staff are available to provide counseling and how such findings will be reported and participants counseled. Thus, it is important that this information be provided to the IRB so that it may carefully balance the risks and benefits pertaining to the specific population, research procedures, and methods used to screen for pregnancy when reviewing protocols and consent/assent procedures.

In the case of minors, the Workgroup acknowledged that sensitivity to parent-child issues was important. To minimize the risks of placing under-age females in a potentially conflictual situation at the time of testing, pregnancy might be mentioned as a reason not to participate at the time of recruitment. This allows the young woman to decline to participate without providing specific information bearing on this

issue. Considerations for screening should take into account whether to screen the minor privately or with the parent or guardian present and whether to inform parents or guardians of the results of such screenings. As part of the assent process, the adolescent should be informed of what will be done with the results of the screening, including any interview data and/or pregnancy testing (consistent with state and local statutes). Sites testing for pregnancy should consider in advance how participants and/or parents will be informed of results, and whether there are personnel on site who are adequately trained to provide counseling. Such considerations should be discussed with the local IRB(s) in advance.

Special consideration is warranted for vulnerable populations, whose members may be less accurate in reporting the possibility of pregnancy, e.g., minors, or potential participants with psychosis or major depression. Added safeguards should be considered for such participants. Leaving decisions about whether to participate up to potentially pregnant adolescents and/or people with severe mental impairments may be unacceptable to IRBs.

Note that the issue of when a minor's health information, including pregnancy screening results, may or must be disclosed to parents or guardians is governed by the Department of Health and Human Service's Health Insurance Portability and Accountability Act (HIPAA) and/or other applicable privacy and state laws. The application of HIPAA would depend upon whether the screening is performed by a HIPAA-covered entity (such as a healthcare provider that conducts certain transactions electronically). HIPAA may also interact with other applicable privacy and state laws. With some exceptions, HIPAA generally requires covered entities to treat parents and guardians of un-emancipated minors as "personal representatives" to whom the minor's records must be disclosed upon request, if the parent or guardian has authority under applicable law (e.g., state law) to act on behalf of the minor with respect to health care decisions. However, where a state law permits a minor to consent to pregnancy treatment without a parent or guardian's consent and the minor does so without parental involvement, this HIPAA requirement may not apply. Note further that state laws may govern mandatory reporting of pregnancy to Child Protective Services, depending on the age of the adolescent, the age of the sexual partner who fathered the child, and the difference in their ages. HIPAA would permit HIPAA-covered entities to disclose patient health information as required by other laws. Researchers should consult their institutional legal counsel for guidance on the parental and other disclosure requirements, if any, that apply to a particular research setting, and the applicable requirements for reporting should be made clear to the adolescent.

Providing the results of a pregnancy test to participants or parents implicates the federal Clinical Laboratories Improvement Act (CLIA) and state laws regulating laboratory testing.

Researchers should consult with legal counsel to ensure that screening involving pregnancy testing is performed in compliance with applicable law.

**A-9. Are there approaches in place for screening for repeat scans?**

The question of screening for repeated scanning arises most commonly in cognitive neuroscience research involving normal volunteers, some of whom may be scanned daily or weekly for some period of time.

The Workgroup discussed whether participants should complete a full screening questionnaire and interview for each scanning session. The Workgroup recognized the value of completing the full screening, i.e., full standard written questionnaire and interview, with appropriate signatures for each scan.

**B. Training, Operating, and Emergency Procedures**

**Are training, operating and emergency procedures in place to help ensure participant safety?**

**B-1. Are specific policies and procedures for training personnel associated with the MRI facility developed and documented?**

Given that the MRI environment presents many potential dangers to untrained or improperly screened individuals, the Workgroup recognized the need for appropriate levels of training for all individuals who operate the scanner and/or have routine access to the MRI suite and for a clearly specified scheme for training and certifying individuals for each level of authorization. A range of options was mentioned for certification, including didactic training, mastery of written materials, and terms of apprenticeship, as well as written and/or practical tests.

The following was discussed as one example of a multi-level training and certification scheme:

**Level I** personnel are defined as those who are authorized to have unsupervised access to the MRI suite, but who lack authority to screen other individuals or to bring other individuals into the scanner facility. Certification at Level I requires training in how to screen oneself, a clear understanding of what is and is not safe in the MRI environment, and knowledge of safety procedures for entering the MRI suite and very basic emergency procedures, e.g., knowledge of whom to call and how to rapidly access appropriate phone numbers. Level I may include cleaning, transportation, security, and anesthesia staff, and any others who may have legitimate reasons to enter the MRI suite unsupervised and thus need to be appropriately trained in safety and emergency procedures.

**Level II** personnel are those who, in addition to Level I certification, are also certified to operate the MR equipment, as well as to screen others for entry into the MRI suite and oversee their presence in the suite and during scanning. They would have more in depth knowledge of MR safety issues including the safety of different materials for the particular environment, the safety guidelines of the applicable IRBs, and where to get additional information if needed.

**Level III** personnel are faculty or senior staff who, in addition to having achieved levels I and II certification, are also certified to train and certify Level I and Level II personnel and are authorized by the facility director to do so. These individuals would have knowledge of the requirements needed to run a safe MRI environment and would be responsible for keeping these requirements updated.

It was felt that researchers should adhere to an accepted national standard of care consistent with safety provisions, such as those of the ACR. Personnel should be trained on all elements relevant to their research practices. In the terms of the ACR guidelines, those operating the scanner should be trained to

Level II status insofar as the guidelines are relevant to their research practices. For many university settings, this may not include use of contrast agents, but will include training in regard to radiofrequency (RF) thermal safety issues, gradient neurostimulation, and auditory concerns.

Sites may design their own training procedures so long as these adhere to nationally established standards of care and encompass the MR potential risks to which participants might be exposed. For example, if a site expects to have a participant undergo MR scanning of the head, MR safety training requirements for the operator of this study would cover biological and mechanical effects of static magnetic fields, safety aspects related to gradient and RF magnetic fields, cryogen usage and safety issues, safety aspects of claustrophobia and other anxiety management, etc. If no sedation, intravenous medication, or MR contrast agents are to be administered, training regarding these areas may not be required.

The Workgroup recognized that principal investigators might have certification at any one of these levels depending on their role in running the study. Regardless of their level of certification, all responsibility for the safety of the MRI examination will at all times rest with the principal investigator and the designated safety officer.

The Workgroup noted the importance of the facility having clearly documented procedures for training and certifying personnel at all levels, for keeping certifications current, and for maintaining comprehensive, up-to-date records regarding the certification status of all personnel associated with, or who have access to, the facility.

**B-2. Are staffing patterns adequate for dealing with emergencies?**

The Workgroup discussed the need to anticipate potential emergencies and to ensure the availability of adequate personnel coverage with which to affect a quick response. The Workgroup felt that the presence of at least two trained staff (at least one of whom had attained Level II status), at all times that a participant or accompanying family member/escort was within an area in which the magnetic field posed a risk (e.g., zones 3 and/or 4 as described below), would help ensure an adequate response to an emergency.

Furthermore, for all cases in which an MR contrast agent was being administered via any route other than by mouth, a duly licensed physician must be on site and readily accessible to handle possible adverse reactions to the administered MR contrast agent. Research involving participants of course necessitates whatever additional (nonspecific to the MR environment) protections are needed to deal with any medical issues, e.g., sedation, cardiac issues, psychiatric issues, etc.

**B-3. Are there clear lines of authority for dealing with safety issues?**

The Workgroup recognized the need for clear lines of authority for dealing with safety issues and felt that a good approach for ensuring this was to designate an on-site safety officer for each scan. The designation of a single safety officer for each scan avoids ambiguity or diffusion of responsibility during an emergency. The Workgroup felt that the equivalent of Level II certification described above was

appropriate for such an individual.

Personnel involved in the study session should be made aware of the designated safety officer for each scan. For example, if there is more than one potential safety officer present, e.g., more than one Level II staff member at a scan, it is important that a single individual be recognized as in charge of safety issues prior to entry into the facility.

**B-4. Are standard procedures for dealing with emergencies developed and documented at the MRI facility and are staff prepared to implement these procedures?**

The Workgroup recognized the importance of having procedures in place for dealing with emergencies, and maintaining staff readiness to deal with potential emergencies especially in non-medical settings. The Workgroup felt that aspects of this preparedness included knowledge of whom to call in the case of emergencies of various sorts, immediate access to the appropriate phone numbers, how to remove a participant from the scanner, transfer the participant onto a stretcher if necessary, evacuate him/her from the scanning suite, and when and how to quench the magnet.

In addition to the importance of emergency preparedness, it is equally important for researchers in non-medical settings to make it explicitly clear to participants-as part of the informed consent procedure-that emergency medical services may not be available onsite. This precaution is to prevent participants from mistakenly interpreting the presence of the MR scanner as evidence that they are in a medical setting with associated emergency medical services.

Related to this point, the Workgroup discussed the merits of additional safety training, such as cardiopulmonary resuscitation (CPR) techniques. However, because there are no known risks of a cardiovascular event specifically associated with exposure to the MRI environment or with being scanned (other than the presence of a pacemaker or an implantable cardioverter defibrillator), the Workgroup did not find any reason to require that personnel associated with a research-dedicated MRI facility be certified as having been successfully trained in CPR. Exceptions to this would include examinations of participants who are otherwise at risk for cardiopulmonary events.

**B-5. Has the MRI site established relationships with emergency resources in the facility and community?**

The Workgroup recognized the importance of establishing relationships with emergency resources within the host institution (e.g., university or medical center), as well as in the community. The Workgroup felt that particularly in non-medical (e.g., university) settings, where emergency workers may not expect to find an MRI facility, the relevant services (such as the fire and police departments) should be made aware of the existence of the facility and its special safety concerns (e.g., personnel cannot enter with air tank). Regular meetings with such personnel were thought to be helpful for ensuring familiarity with the facility and its safety considerations and for reviewing its emergency procedures. Also thought to be helpful was the practice of educating public safety and risk management groups at the institution that houses the MRI facility with respect to the MRI facility's special considerations.

**B-6. What centralized system exists at the MRI facility for reporting, managing and archiving incidents and adverse events associated with scanning?**

The group discussed the need for a system for reporting and recording incidents and adverse events associated with scanning and its value for improving safety. Such a system would allow researchers to file incident reports and make the archive available for consultative purposes. It was also felt important that all breaches of safety procedures and other safety-related incidents should be reported, not just those involving actual adverse outcomes. This would provide useful information about the frequency of "near misses" and other occurrences that might reveal weaknesses in safety procedures and/or signal a decline in safe practices.

Researchers in clinical facilities must also be aware of any requirements imposed by the facility's risk management reporting process and of any legal constraints upon the disclosure of incident information to individuals outside of the institution.

**C. Physical Facilities**

**What protections are in place in the facility to ensure safety in those areas affected by the magnetic field? What special restrictions, equipment and experts for evaluating the MR safety of devices does the facility provide?**

**C-1. What methods are in place to control and regulate access to the MRI suite (control room and magnet)?**

Some, but not all, facilities use a standard "zoning system" such as that outlined in the ACR guidelines, to control and regulate access to the control room and magnet for safety purposes. The ACR zoning system is described below as one example of a system that can be used. Whatever system is adopted should provide protections comparable to those described below.

**Zone 1** includes all areas that are freely accessible to the general public, and is typically outside of the MRI environment (i.e., that portion of the environment in which the magnetic field poses a risk).

**Zone 2** is the interface between the publicly accessible, uncontrolled zone 1 and the strictly controlled zones 3 and 4 (which pose a risk). Typically, participants are greeted in zone 2 and their movement throughout zone 2 is under at least intermittent supervision of MR personnel. This area is typically used for initial contact and screening.

**Zone 3** is the region through which there is free, physically unrestricted access to areas that pose a risk due to the presence of the MRI scanner itself (which is in "zone 4" - see below). Zone 3 will always include, but may extend beyond, areas that pose a risk. For example, zone 3 may include the console room, equipment room(s), and preparatory areas, which may or may not fall within the fringe fields (five

gauss line) of the magnet, but all of which have physically unrestricted access to areas that are affected by the magnet's electrical and/or magnetic fields. The boundaries of the five gauss line should be clearly and visibly marked within zone 3 (e.g., with a red line on the floor and with signs indicating the presence of the field and associated risks), so that it is clear whenever someone is approaching an area of a five gauss or greater exposure level.

In some cases, zone 3 may involve discontinuous regions. For example, the static fringe fields of the magnet may extend beyond the physical confines of the scanning suite, into areas that are discontinuous from the scanner facility (e.g., into courtyards, roofs, or other areas neighboring the building). Zone 3 encompasses these additional areas. When zone 3 involves areas that fall outside of the scanning facility, it is imperative that these additional areas and the risks they present be marked clearly and visibly.

Access to zone 3 should be strictly physically restricted, ensuring that there is fully regulated access to all areas that pose any risk due to the presence of the magnet or its associated electromagnetic fields. This need to restrict access applies equally to the sorts of discontinuous areas mentioned above. It is imperative that these additional areas and the risks they present be marked clearly and visibly and that without exception (and in accordance with their status as zone 3 areas), they be physically restricted from inadvertent access from any non-MR personnel.

Access to zone 3 should be controlled by Level II MR personnel (with the exception that Level I personnel are permitted to screen themselves and enter without supervision; see B-1 above). No unscreened non-MR personnel are allowed access to zone 3. "Non-MR personnel" are those not trained or certified with respect to MRI facilities at any level. Access should be restricted with key locks, pass key locking systems or other reliable, physically restricting methods that can differentiate between MR personnel and non-MR personnel. Combination locks are discouraged, since combinations can be too easily shared with unauthorized personnel.

**Zone 4** is the physical confines of the room housing the MRI scanner itself. By definition, zone 4 always falls within zone 3. The primary significance of zone 4 pertains to the risks due the attractive forces of the static field of the magnet (inducing projectiles), and the effects of the time varying gradient and RF fields when imaging is in progress. The entry to zone 4 should be clearly marked, with a sign indicating the presence of and potential danger due to the magnet.

**C-2. How are areas affected by the MR system demarcated? Do danger signs clarify for whom these areas pose risks?**

The Workgroup recognized the importance of clearly demarcating the areas affected by the magnet and for warning persons for whom the magnetic fields pose health risks. Examples offered of appropriate signs are those indicating "Danger" and "The magnet is always on" that are typically used to demarcate affected areas and make clear what types of persons are at risk (e.g., those with pacemakers). Other examples are floor markings and/or barriers clearly delimiting the five gauss line.

**C-3. Is MR-safe fire extinguishing equipment available and appropriately located in the MRI suite?**

The Workgroup acknowledged that storing MR-safe fire extinguishing equipment in the MRI suite (i.e., in either zones 3 and/or 4 as described above) ensures immediate access and therefore enhances safety. Although the risk of a fire is small, the ready availability of such equipment would prove extremely useful in such a rare event.

The Workgroup further felt that storing such equipment in the suite helps protect against the risk of having unsafe equipment enter the suite.

**C-4. How will the MR safety of devices for the MRI research facility be assured?**

Most devices used as supplementary equipment in MR settings (e.g., surface coils, cardiac recording devices, etc.) are Food and Drug Administration (FDA)-approved. However, in cases where this is not the case (e.g., non-FDA-approved devices developed for research, such as devices for displaying stimuli or recording behavioral responses from the participant), the Workgroup recognized the importance of specifying and following clear guidelines for ensuring the safety of their use in research settings. Consistent with such practices would be a careful review by individuals competent to evaluate the safety of such devices and the provision of a description of these devices and procedures for evaluating their safety to the IRB.

Toward these ends, the Workgroup recognized the value of having access to one or more consultants with the expertise needed for evaluating the MR safety of all devices used in the facility (e.g., non-standard coils, ancillary devices for presenting stimuli and recording responses, etc.). This technical expert or group should be competent to decide whether IRB, FDA and/or external safety consultation are needed, that were not provided by the manufacturer of the scanner, for devices that are to be used with it.

Among the safety issues that the Workgroup felt were important to consider were the magnetic properties of the device, as well as the potential for creating current loops that can overheat and produce burns. The proper operational aspects of a given device relative to the MRI environment should also be considered.

**C-5. Are adequate oxygen concentrations in the MRI suite ensured?**

The FDA states that: "The oxygen concentration in accessible areas should not be allowed to go below acceptable levels." Oxygen concentration can be monitored using oxygen sensors in the MRI suite, such as those installed by the scanner manufacturers.

**D. Scanning/Participant Health Variables**

**What standard procedures are in place in the MRI facility for protecting the participant's health, the safe operation of the scanner, and the reporting and archiving of incidents relevant to these issues?**

**D-1. What standard procedures are documented and in place for ensuring safety?**

The Workgroup recognized the value of clearly documenting all procedures for the safe operation of the scanner and the handling of adverse events and for making this documentation readily accessible to all personnel associated with the facility. These procedures and their documentation would be an important focus of training for Level II personnel (see Section B-1 above).

The Workgroup felt that standard procedures should also be in place for the detection and reporting of incidental findings and other specific health and safety-related issues as described below.

**D-2. Are participants always visible to and in hearing contact of the MRI operator and allowed to terminate the scan and exit the scanner at any time?**

The Workgroup felt it important that the participant be visible to and in hearing contact of the MRI operator at all times. The Workgroup further acknowledged that the ability to voluntarily terminate a study at any time during scanning is in accord with the federal regulations for the protection of human subjects (Code of Federal Regulations Basic Health and Human Services Policy for Protection of Human Research Subjects: 45 CFR 46.116 (a) (8)).

**D-3. Is hearing adequately protected?**

The Workgroup acknowledged the importance of using earplugs or other hearing protection during scanning to attenuate noise levels.

Acoustic noise levels during scanning generally fall between 65 and 95 decibels (dB), but can reach more than 120 dB. Acoustic noise levels vary depending on the pulse sequence, field strength, and other factors. Hearing protection may lower these exposures by about 20 dB, but this may vary according to the type of protection being used. Risks will differ given single versus repeated exposures, scan duration and the effectiveness of the protection.

The Workgroup recognized the importance of facilities working within standards specified by the U.S. Occupational Safety and Health Administration (OSHA 29 CFR 1910.95), which take into account the length and level of exposures. If noise levels exceed those specified below, attenuation must be used to decrease exposures to within these limits. The term dBA, or A-weighted decibels, refers to the sound level when measured on an A scale of a standard sound level meter at slow response.

| **Hours per day** | **Sound level dBA slow response** |
|---|---|
| 8 | 90 |
| 6 | 92 |
| 4 | 95 |
| 3 | 97 |
| 2 | 100 |

| | |
|---|---|
| 1 1/2 | 102 |
| 1 | 105 |
| 1/2 | 110 |
| 1/4 or less | 115 |

OSHA also specifies that exposure to impulsive or impact noise should not exceed 140 dB peak sound pressure level. In addition, apart from these guidelines, a weighted root mean square sound pressure level greater than 99 dBA with hearing protection in place poses a significant risk (according to a FDA document: Criteria for Significant Risk Investigations of Magnetic Resonance Diagnostic Devices, issued on July 14, 2003).

For any research participant, any MR imaging sequence that has not received FDA approval should only be executed with hearing protection in place unless it can be documented that the anticipated auditory levels would be clearly below established and acceptable thresholds and guidelines.

The issue of medical conditions that might increase risk for hearing loss as a result of MR-generated acoustic noise was discussed. The Workgroup was not aware of any data to indicate that conditions such as tinnitus or the loss of stapedial reflexes might increase susceptibility to noise-induced hearing loss due to MR scanning, if adequate hearing protection is used to attenuate acoustic noise below allowable limits.

**D-4. Do the research scans fall within FDA guidelines for magnet strength, specific absorption rate (SAR), gradient fields' rates of change, and acoustic noise?**

In 2003, the FDA specified the following nonbinding guidelines for MRI safety (http://www.fda.gov/cdrh/ode/guidance/793.html):

Main static magnetic field: For adults, children, and infants greater than one month of age, field strengths greater than 8T are presently considered to pose a potential significant risk. For neonates (infants under one month of age), field strengths greater than 4T are presently considered to pose a potential significant risk.

Specific absorption rate (SAR): The following are considered significant risks (expressed in watts per kilogram):

Whole body average dose over 15 or more minutes: 4 W/kg
Head average dose over 10 or more minutes: 3 W/kg
Head or torso dose per gram of tissue over 5 or more minutes: 8 W/kg
Extremities dose per gram of tissue over 15 or more minutes: 12 W/kg

Gradient fields' rates of change: Any rate of change of gradient fields (dB/dt) sufficient to produce severe discomfort or painful nerve stimulation is considered a significant risk.

Acoustic noise: A peak acoustic noise level over 140 dB is considered significant risk, as is a weighted-root-mean sound pressure level greater than 99 dBA with hearing protection in place. (In addition to the FDA guidelines, OSHA guidelines specify the lengths of time at which various noise levels present risks to hearing [see D-3]).

Because the FDA considers MRI/functional MRI research studies a nonsignificant risk, no investigational device exemption (IDE) is required. (See Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors; Significant Risk and Nonsignificant Risk Medical Device Studies: http://www.fda.gov/oc/ohrt/irbs/devrisk.pdf). The regulations for studies using devices such as MR scanners do not require physician prescriptions for clinical procedures that are done as part of clinical research. The responsibility for safety and the protection of human participants rests with the local IRB and the informed consent process (21 CFR Part 812.5, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm).

The Workgroup felt that no special actions were needed for research scans that fall within the FDA guidelines concerning magnet strength, pulse sequences (gradient fields' rates of change), SAR, and peak sound levels (except see D-3 concerning acoustic noise). Under conditions in which research scans fall outside of FDA guidelines, the Workgroup felt it important to make the IRB aware of this and inform participants accordingly. In such instances, the Workgroup recognized the need for consent language that would need to be very different from that used when working within the FDA ranges.

**D-5. What special precautions are in place for infant scanning?**

The Workgroup discussed the need to protect against loss of body heat (hypothermia) and for physiologic monitoring of heart rate and oxygen saturation when scanning infants.

To protect against hypothermia, the Workgroup recognized the value of monitoring core temperature, swathing the infant tightly, using warming packs, turning off fans, and increasing the temperature in the scanning room, as well as limiting the scan time to one hour to help prevent heat loss. The Workgroup also recognized that significant changes from baseline in heart rate and oxygen saturation warrant terminating the scan.

**D-6. Is there a clear protocol in place for dealing with incidental findings?**

The Workgroup recognized the importance of having a clear protocol for dealing with incidental findings prior to the start of the research. Important aspects of this protocol were felt to include a consent form that clearly distinguishes research from clinical scans, that explicitly discusses the potential for incidental findings and associated risks, that informs the participant as to whether or not the scans will be reviewed by a clinician qualified to render a radiological interpretation, and that describes the path that will be taken in the event that an incidental finding occurs. The Workgroup viewed these as consistent with the need for having a protocol in place for dealing with incidental findings in general, including non-imaging-related incidental findings.

The Workgroup recognized the importance of not having participants confuse a research scan with a

clinical scan. This might be addressed with consent language that states that the research scan they are receiving is not a clinical scan (e.g., may not be of clinical quality or thoroughness) to avoid any inference that the scan rules out a medical problem. Consent language used in a non-medical setting might make it clear that the setting is not a medical one.

Further, despite the fact that the scan may not be of clinical caliber and/or that there may be no clinically trained investigators involved in the research, the Workgroup felt it important that participants be informed of the possibility that an abnormality may be detected or suspected in the process of the research, the clinical significance of which may not be clear. In this regard, the risks associated with false positives are important to recognize and acknowledge, including unnecessary worry, expense for medical follow-up, and possibly unpleasant or invasive medical tests.

The Workgroup considered that a clear protocol for dealing with incidental findings should be outlined and in place (as discussed above) including the stipulation that the participant will be fully informed concerning the policies and procedures in place concerning potential incidental findings. It will be up to the IRB to review and approve the protocol.

In instances where the plan does not include a clinical review, if a researcher does notice something believed to be out of the ordinary on a scan, the Workgroup considered that the researcher could alert the participant to it. The researcher could either share the information with a physician with the participant's (or parent/legal guardian's) consent, or encourage the participant to seek a clinical referral.

**D-7. Has a qualified individual been identified who will report any incidental findings to participants?**

As stated above, there should be a protocol for dealing with incidental findings that includes a plan for reporting suspected findings to the participant. The protocol should identify appropriate personnel or consultants who will report such findings to the participant.

An individual responsible for reporting incidental findings should be knowledgeable of the facility's policies with regard to the detection and reporting of incidental findings and capable of conveying the potential significance of the findings and possible need for clinical follow-up to the participant effectively and with sensitivity.

The Workgroup concluded that if a physician were involved in the study, he/she would be an appropriate informant. In non-medical settings, a principal investigator or other responsible and qualified investigator may be an appropriate person to serve in this role.

**D-8. Has the need for additional safeguards for vulnerable populations, such as children, been considered and resolved?**

Members of the Workgroup expressed some concern that vulnerable populations, such as children, might warrant additional protections. For example, the Workgroup considered cases in which an incidental

finding of potential clinical significance is merely shared with a parent who may not fully appreciate the need for follow-up (e.g., asymptomatic malformation that was causing sub-clinical seizures and thus impacting the child's learning). In anticipating this type of situation, one might consider obtaining permission to inform the child's primary care physician as part of the consent process.

Other issues, not unique to MR research, include suspected child abuse or neglect, e.g., the latter potentially associated with a parent's failure to address a child's medical needs. During a neuroimaging study, an MRI procedure may yield findings suggestive of abuse. In such instances, state laws mandating the reporting of suspected abuse or neglect may become relevant.

**D-9. Does the research involve repeated scanning?**

The Workgroup agreed that safety concerns do not dictate any set limits on the duration or frequency of scanning. The duration of a scanning session was felt to be limited only by the participant's ability to remain still and tolerate the scanning conditions. The appropriateness of protocols involving long or frequent scans will be determined by the local IRB.

The Workgroup knew of no harmful biological effects of short- or long-term exposure to static magnetic fields. The National Council on Radiation Protection and Measurements Commentary No. 18 (2003) on the biological effects of modulated radiofrequency fields concludes "that the scientific literature related to modulation-dependence of biological effects of RF energy is not sufficient to draw any conclusions about possible modulation-dependence of health hazards of RF fields nor is there any apparent biophysical basis from which to anticipate such hazards apart from very intense RF pulses produced by some specialized military equipment."

However, guidelines to prevent excessive heating and burns associated with magnetic resonance procedures can be found at http://www.imrser.org/PaperPDFlist.asp?pgname=Guidelines.

**D-10. Are subjects with major contraindications to scanning being studied?**

The Workgroup agreed that MR scanning of participants with major contraindications to scanning is only appropriate when there is a clinical need or the research is targeted at a special population in which potential benefits have been appropriately weighed against the risks. Major contraindications might include, but are not limited to, metal in the eyes, cardiac pacemakers, implanted cardioverter defibrillators, neurostimulation systems, and cochlear implants. In such instances, specific risk/benefit ratios would, of course, be addressed by the relevant IRB, based on review of inclusion/exclusion criteria included in study protocols.

**D-11. Are participants with "minor" contraindications to MR scanning being studied?**

The Workgroup discussed the situation in which participants with "minor" contraindications to scanning are studied. A working definition of a "minor" contraindication is one which is unlikely to pose a risk, but

which may, albeit infrequently and if not carefully monitored, result in injury.

The Workgroup felt that the participant should be informed of the potential risks involved in such "minor" contraindications and recognized the value of appropriate precautions being instituted.

The example most thoroughly discussed was that of tattoos. Given that there is some risk of burns, the group considered the value of carefully monitoring the participant, although it has also been noted that burns can occur before the participant notices them or develop after the participant is removed from the scanner. Alternatively or in addition, ice packs or cold compresses might be prospectively placed on any tattoo in the volume about to undergo RF irradiation in the MR imaging process, although there is no consensus on the efficacy of this measure.

**D-12. What should be done when a participant presents with an implant or device for which safety information is unclear or unavailable?**

The Workgroup acknowledged that participants with implants or devices for which safety information is unclear or unavailable should not be scanned.

Ready access to a trustworthy and up-to-date list of devices and information on their MR safety was felt to be most useful (see www.MRIsafety.com). For participants with devices for which information is unavailable, the group agreed that the safest thing to do is to exclude the participant from study.

**D-13. Are participants being scanned at field strengths for which devices in question have been determined to be acceptable for MR procedures?**

The group recognized that implants and devices that have acceptable MR conditions established at 1.5T may not be safe at 3T. Given that field strengths as high as 7T and 8T are in use in research settings, this may mean excluding subjects with implants and devices due to lack of safety data at higher fields.

**D-14. What procedures for documenting and reporting incidents pertaining to the safe operation of the facility are in place?**

As noted in Section B-6, the Workgroup felt that a facility should have clearly defined procedures for documenting and reporting all incidents or near incidents that pertain to the safe operation of the facility. Such incidents include, but are not limited to, adverse events involving the health of a participant that are required to be reported to the IRB, institutional officials, funding agencies, FDA or others. For example, identified failures of participant screening or incidents in which objects have been drawn into the magnet should be documented, even when these have not resulted in an injury. This helps ensure an adequate database of information upon which existing procedures (such as screening and training) can be evaluated and potential revisions of policy can be based.

**E. Context-Specific Considerations: Medical vs. Non-Medical Settings**

**E-1. Are there any context-specific considerations or modifications of safety procedures applicable to the setting?**

The Workgroup recognized that while safety considerations are paramount in any setting, the implementation of safety procedures might differ somewhat based on the context or environment.

There are generally three contexts for MRI, but particularly for functional MRI (fMRI) scanning: the clinical environment, the dedicated research facility in a medical setting, and the non-medical environment (e.g., a psychology or neuroscience department at a university without a medical school). The Workgroup recognized that the last of these presents the greatest challenge in terms of devising appropriate procedures for ensuring safety, as fewer procedures are likely to be in place independent of the research environment.

In considering the above categories of safety issues, the Workgroup felt that:

For **MRI screening**, all of the same recommendations and procedures apply to all settings.

Regarding **staffing and personnel issues**, in the non-medical setting, the protocol and procedures to deal with medical emergencies will need to be in place, and any relationship with a medical partner will need to be explicated.

While Level II personnel in the medical setting will generally include ACR-certified technologists, this may not generally be the case in non-medical research settings. Some facilities may use a hybrid model, such as MR technologists during regular working hours and other suitably trained and certified personnel for evening, nights and weekend operations.

Similarly, the procedures for certification may differ by setting. In non-medical settings, senior staff and principal investigators may do the certification.

Regarding **physical facilities** in non-medical settings, institutional officials and personnel not affiliated with the MRI facility may be unaware of the existence of the MRI scanner within their institution or facility and may not be knowledgeable concerning MRI facilities and their safety requirements. This may place a greater burden on the MRI facilities manager for identifying and managing training needs and organizing emergency services.

Concerning **scanning/participant health variables**, to the extent that participants are patients or individuals with medical conditions, the IRB and principal investigator assume responsibility for reviewing inclusion/exclusion criteria and ensuring the safety of participants, as in any research. Participants with medical conditions that may precipitate an emergency during scanning (e.g., epilepsy) require additional planning, as in any research environment. This includes a clear specification of the procedures to be followed in the scanning environment in the event of an emergency.

## F. Additional Data Needs and Updating

**The following questions and issues were deemed by the Workgroup to be in need of additional data, attention, and/or guidance.**

### F-1. Incidental findings:

What is the base rate of incidental findings on a sufficiently large sample size to ensure reliable estimates and, of these, how many are clinically significant? What is the likelihood of missing a clinically significant finding when radiologists or other physicians do not routinely review research scans?

What is the likelihood of detecting a finding that eventually is determined to be clinically insignificant (though it may have caused anxiety and expense due to further testing)?

It is possible that relevant actuarial data exist but are not properly assembled. A retrospective study, in which a neuroradiologist read scans from a university facility in which staff have been documenting incidental findings detected by non-physicians and the participant informed, may yield an answer.

### F-2. Pregnancy:

Does MR scanning pose a risk to the fetus? Are there data from women who were scanned when unaware they were pregnant and the consequences, if any, that can be identified?

Data on this issue bears on the issue of risks associated with testing adolescents for pregnancy vs. risks of scanning pregnant adolescents. Testing and interviewing adolescents creates ethical issues concerning the possible disclosure of results to parents and counseling in the event of positive tests.

### F-3. MR incident reporting:

What are the rates of incidents in which metallic objects have entered the MRI suite in medical facilities vs. non-medical facilities?

How should these incidents impact safety recommendations?

How might a centralized system for reporting, managing and archiving incidents and adverse events associated with scanning be developed? A centralized system would be useful for collecting data with which to improve safety. Researchers could then systematically file incident reports and access this sort of archive for consultative purposes.

How can existing systems for reporting adverse events contribute to a centralized archive and safety recommendations?

Although IRBs currently have reporting requirements for adverse events, these are non-uniform. Under the Common Rule (45 CFR Part 46, Subpart A), an IRB must require reporting of all unanticipated problems resulting in risks to participants or others, even if there is no actual injury, as these hold implications for safety. However, IRBs may not have procedures in place to adequately inform investigators of this reporting requirement. A breach (i.e., metal ends up where it should not be) without resulting injury may well not be documented.

Technical breaches (e.g., a paperclip enters the scanner, but no participant is present and therefore there is no risk to a participant) remain distinct from those required to be reported to the IRB. Nonetheless, some facilities may choose to have a mechanism in place for reporting these technical breaches for analytic purposes, both because such data may prove useful in maintaining the quality of the equipment and also in further improving safety.

Actuarial data provided on the web might balance the graphic nature of accidents currently posted there. Attention generally focuses on projectiles, but burns are a more frequent adverse event. Data of this sort may help to focus sites on areas in need of increased attention and precautions.

**F-4. Repeated scanning:**

What data exist concerning the biosafety of repeated scanning?

What data are needed to establish a lack of threshold effects, i.e., adverse health effects seen only when some critical threshold of exposure is crossed as compared to effects seen with incremental exposures?

**F-5. Use of high field magnets in pediatric neuroimaging:**

Is there a need for additional data on the effects of high field magnets on pediatric participants (e.g., potential for heating in children at 3T or higher)?

**F-6. Experimental devices:**

What guidelines exist for the technical testing of non-FDA approved coils and devices, including ancillary devices designed to present stimuli and record responses in fMRI research?

Do individual sites, e.g., non-medical sites, have the authority to test and approve coils and other devices for use in their facilities? Are they required to adhere to commercial FDA standards?

**F-7. Dental appliances:**

The types of dental braces and retainers frequently worn by adolescents appear to be changing fairly rapidly with advances in orthodontics. Participant reports of heating in some instances raise issues of safety. In addition, the issue of which dental appliances create artifacts in brain images is also of interest.

Longitudinal pediatric research frequently runs into delays caused by dental braces and other appliances, as researchers often assume that these devices will create significant artifacts. Yet, scanning some children and adolescents with dental braces has yielded high quality MR brain images. Access to data for the MR conditions of various dental devices would be helpful.

## References


American Society for Testing and Materials (ASTM) International. (2005). Designation: F 2503-05. *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*. West Conshohocken, PA: ASTM International.

Kanal, E., Borgstede, J.P., Barkovich, A.J., Bell, C., Bradley, W.G., Etheridge, S., Felmlee, J.P., Froelich, J.W., Kaminski, E.M., Keeler, E.K., Lester, J.W., Scoumis, E.A., Zaremba, L.A., & Zinninger, M.D. (2002). American College of Radiology white paper on MR safety. *American Journal of Roentgenology*, 178, 1335-1347.

Kanal, E., Borgstede, J.P., Barkovich, A.J., Bell, C., Bradley, W.G., Etheridge, S., Felmlee, J.P., Froelich, J.W., Hayden, J., Kaminski, E.M., Lester, J.W., Scoumis, E.A., Zaremba, L.A., & Zinninger, M.D. (2004). American College of Radiology white paper on MR safety: 2004 update and revisions. *American Journal of Roentgenology*, 182, 1111-1114.

National Council on Radiation Protection and Measurements (NCRP) (2003). Commentary No. 18: *Biological effects of modulated radiofrequency fields*. Retrieved December 6, 2006, from www.ncrponline.org.

Shellock F.G. (2001). *Magnetic resonance procedure: health effects and safety*. Boca Raton, FL: CRC press.

Shellock F.G. (2006). *Magnetic resonance safety, implants, and devices* (2006 ed.). Los Angeles, CA: Biomedical Research Publishing Group.

Shellock, F.G.,& Crues, J.V. (2004). MR procedures: Biologic effects, safety, and patient care. *Radiology*, 232, 635-652.


## MR Safety and Ethics Resources

**Publications:**


Illes, J., Kirschen, M.P., Edwards, E., Stanford, L.R., Bandettini, P., Cho, M.K., Ford, P.J., Glover, G.H., Kulynych, J., Macklin, R., Michael, D.B., & Wolf, S.M. (2006). Ethics. Incidental findings in brain imaging research: What should happen when a researcher sees a potential health problem in a brain scan from a research subject? *Science*, 311 (5672), 783-784.

Illes, J., Kirschen, M.P., Karetsky, K., Kelly, M., Saha, A., Desmond, J.E., Raffin, T.A., Glover, G.H., & Atlas, S.W. (2004). Discovery and disclosure of incidental findings in neuroimaging research. *Journal of Magnetic Resonance Imaging*, 20 (5), 743-747.

Kanal, E., Borgstede, J.P., Barkovich, A.J., Bell, C., Bradley, W.G., Etheridge, S., Felmlee, J.P., Froelich, J.W., Hayden, J., Kaminski, E.M., Lester, J.W., Scoumis, E.A., Zaremba, L.A., & Zinninger, M.D. (2004). American College of Radiology white paper on MR safety: 2004 update and revisions. *American Journal of Roentgenology*, 182, 1111-1114.

Kanal, E. (2004). Clinical utility of the American College of Radiology MR safe practices guidelines. *Journal of Magnetic Resonance Imaging*, 19, 2-5.

Kanal, E., Borgstede, J.P., Barkovich, A.J., Bell, C., Bradley, W.G., Etheridge, S., Felmlee, J.P., Froelich, J.W., Kaminski, E.M., Keeler, E.K., Lester, J.W., Scoumis, E.A., Zaremba, L.A., & Zinninger, M.D. (2003). ACR blue ribbon panel response to the ADJR commentary by Shellock and Crues on the ACR white paper on MR safety. *American Journal of Roentgenology*, 180, 31-35.

Kanal, E., Borgstede, J.P., Barkovich, A.J., Bell, C., Bradley, W.G., Etheridge, S., Felmlee, J.P., Froelich, J.W., Kaminski, E.M., Keeler, E.K., Lester, J.W., Scoumis, E.A., Zaremba, L.A., & Zinninger, M.D. (2002). American College of Radiology white paper on MR safety. *American Journal of Roentgenology*, 178, 1335-1347.

Katzman, G.L., Dagher, A.P., & Patronas, N.J. (1999). Incidental findings on brain magnetic resonance imaging from 1000 asymptomatic volunteers. *Journal of the American Medical Association*, 282, 36-39.

Shellock, F. G. Screening Patients for MR Procedures and Individuals for the MR Environment. (Screening Questionnaires included). Retrieved on December 6, 2006 from www.MRIsafety.com

Shellock, F.G. & Crues, J.V. (2004). MR Procedures: biologic effects, safety, and patient care. *Radiology*, 635-652.

Shellock, F.G. & Crues, J.V. (2002). MR safety and the American College of Radiology white paper. *American Journal of Roentgenology*, 178, 1349-1352.

## Websites:

- Food and Drug Administration: (www.fda.gov/cdrh/ode/guidance/793.pdf)
- International Society for Magnetic Resonance in Medicine (ISMRM): (www.ismrm.org)
- Institute for Magnetic Resonance Safety, Education, and Research: (www.IMRSER.org)
- Information Resource for MRI Safety: (www.mrisafety.com)

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## Appendix 1.

**New Terminology With Regard to Magnetic Resonance Imaging (MRI) and Implants and Devices**

In 1997, the Food and Drug Administration (FDA), Center for Devices and Radiological Health proposed definitions for the terms "MR safe," "MR compatible," etc. defined below. However, the FDA did not mandate retesting and re-labeling of implants and devices that had already received approved labeling using older terminology. Thus, while the new terms will be useful for all present and future MR safety testing and labeling, more general terminology has been used in the preceding report.

Reference: ASTM International, Designation: F 2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 19428, 2005.

The new terms, MR Safe, MR Conditional, and MR Unsafe are defined by the above ASTM document, as follows.

**MR Safe**: an item that poses no known hazards in all MRI environments. Safe items include non-conducting, non-magnetic items such as a plastic Petri dish. An item may be determined to be MR Safe by providing a scientifically based rationale rather than test data.

**MR Conditional**: an item that has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use. Field conditions that define the specified MRI environment include static magnetic field strength, spatial gradient, dB/dt (time varying magnetic fields), radio frequency (RF) fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item, may be required.

For MR Conditional items, the item labeling will include results of testing sufficient to characterize the behavior of the item in the MRI environment. In particular, testing for items that may be placed in the MRI environment should address magnetically induced displacement force and torque, and RF heating. Other possible safety issues include but are not limited to, thermal injury, induced currents/voltages, electromagnetic compatibility, neurostimulation, acoustic noise, interaction among devices, and the safe functioning of the item and the safe operation of the MR system. Any parameter that affects the safety of the item should be listed and any condition that is known to produce an unsafe condition must be described.

**MR Unsafe:** an item that is known to pose hazards in all MRI environments. MR Unsafe items include magnetic items such as a pair of ferromagnetic scissors.

September 14, 2005
Bethesda, MD

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