

Use of Magnetic Resonance Imaging (MRI) in Management of Mild Traumatic Brain Injury (mTBI)/Concussion in the Deployed Setting

Original Release/Approval	02 Aug 2011	Note: This CPG requires an annual review.	
Reviewed:	Jul 2011	Approved:	4 Aug 2011
Supersedes:	This is a new CPG and must be reviewed in its entirety.		
<input type="checkbox"/> Minor Changes (or)	<input type="checkbox"/> <i>Changes are substantial and require a thorough reading of this CPG (or)</i>		
<input type="checkbox"/> Significant Changes			

1. **Goal.** To provide updated guidance for the use of Magnetic Resonance Imaging (MRI) capability in the continuum of care in the diagnosis, evaluation, treatment, follow-up and return to duty of mild traumatic brain injury (mTBI) patients.
2. **Background/Introduction.**
 - a. In December 2006, the first mTBI acute management algorithms in military operational settings were released as part of a Clinical Practice Guideline (CPG) document. Since then, several memorandums were released, algorithms have undergone several revisions, and more research has been done. Last updated version was 21 Nov 2008 at the request of Joint Theater Trauma System (JTTS) and CENTCOM leaders. The terms mTBI and concussion are used interchangeably in the literature, and for the purpose of consistency, concussion is used throughout these recommendations.
 - b. On June 21, 2010, Directive Type Memorandum (DTM) 09-033, "Policy Guidance for Management of Concussion/Mild Traumatic Brain Injury in the Deployed Setting" was signed by the Deputy Secretary of Defense. This For Official Use Only (FOUO) document was established to address battlefield concussion, a major deployment concern of the military. The DTM established several mandatory events requiring concussion evaluations and reporting with aims to improve early detection, appropriate treatment, and avoidance of second concussion before recovery. FOUO algorithms were also established for combat medic/corpsman, initial provider, and multi-disciplinary teams including algorithms for comprehensive evaluations of concussion and recurrent concussion. The most current algorithms referenced in the DTM for the deployment environment can be accessed via link to following website: http://www.dtic.mil/whs/directives/corres/pdf/DTM-09-033_placeholder.pdf.
 - c. Concussion per DoD criteria is defined as blow or jolt to head or blast exposure followed by alteration of awareness/consciousness or complete loss of consciousness less than 30 minutes. ("VA/DoD Clinical Practice Guideline for Management of Concussion/Mild Traumatic Brain Injury," 2009).
 - d. Computerized Tomography (CT) scan is considered standard of care for imaging patients with head injury and suspected intracranial pathology. CT is a highly sensitive test for the rapid diagnosis of intra-cerebral injury requiring urgent neurosurgical intervention. In the civilian literature, up to 15% of patients who are alert and have grossly normal neurological function including a Glasgow Coma Scale score of 15 will have an acute brain lesion on CT, while less than 1% will have a lesion that requires neurosurgical intervention.

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- e. Magnetic Resonance Imaging (MRI) offers a higher resolution image of the brain and is generally more sensitive for detecting intra-cerebral pathology. MRI at 1.5Tesla has been reported to detect different markers of cerebral injury in 15-30% of patients with a normal head CT. MRI offers a particular advantage in detecting chronic lesions in white matter associated with concussion-related symptoms, such as difficulty with memory and attention that can continue for weeks or months after the injury. The sensitivity of MRI makes it an informative imaging tool for concussion in certain circumstances to support DTM 09-033 Clinical Practice Guidelines (CPGs) for Comprehensive Concussion Algorithm 3A and Recurrent Concussions Evaluation Algorithm 4A (defined as 3 documented concussions in 12 month span) at a Level III facility with this capability. Both algorithms have indications for neuroimaging to assist providers in clinical decision making.
- f. MRI has additional specific limitations in theater, as a diagnostic tool at a few select Role III facilities. MRI has unique requirements for its safe use with patients which require additional technician training and strict adherence to MRI-specific safety protocols. Clinically irrelevant artifacts are more common with MRI as well. These limitations necessitate a per-individual assessment of the risks and benefits of pursuing an MRI scan for concussion.

3. Operational Tenets

- a. As stated in 2006 and 2008 reports, mission requirements may supersede individual member welfare in certain operational environments as determined by combatant commanders' consideration of operational objectives, risks, and costs. The small risk of deterioration in patients who present with concussion must be considered and weighed against the limited availability of neuroimaging and neurosurgical treatment.

4. Methodology

- a. The Defense and Veterans Brain Injury Center Working Group in 2008 included a diverse, multi-disciplinary membership from Veterans Affairs, Department of Defense, civilian subject matter experts, special operations staff, and deployed providers. This Working Group had recommended revision of CPGs incorporating current literature, knowledge of operation conditions, consensus expert clinical experience and best practice reports.
- b. Further revisions of these 2008 medic/corpsman, provider specific and comprehensive concussion CPGs were made in 2009; and addition of recurrent concussion CPG was added in 2010 in conjunction with release of DTM 09-033. The term CPG is used in congruence with similar JTTS management recommendations, although it is acknowledged that there remains not enough Class I studies to support a formal evidence-based guideline.

5. Evaluation and Management of Concussion in the Deployed Setting with MRI

- a. **Use of MRI in management of concussion in the deployed setting.** Current 2010 DTM CPGs for management of concussion in deployed setting includes careful examination for red flags at Level I and Level II that may indicate more severe injury. Neuroimaging is important in the evaluation of patients with these red flags and can be completed at Role III with CT or MRI imaging if available and not contraindicated. CT remains rapid, readily available diagnostic tool that is very sensitive for acute intra-cerebral hemorrhage and a standard imaging study in acute trauma protocols unlike MRI. CT also avoids risk of MRI with ferromagnetic materials such as in fragments which can be common in improvised explosive

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devices. In specific instances, such as the evaluation of persistent cognitive and behavioral impairments following concussion, MRI may offer an advantage over CT.

- b. Providers at Role III may consider obtaining MRI when available and not contraindicated if:
 - 1) Service member sustained a concussion with alteration of consciousness (AOC) greater than 15 minutes and has persisting or worsening symptoms after 72 hrs.
 - 2) Service member sustained concussion with loss of consciousness <30 minutes and has persisting or worsening symptoms after 72 hrs despite a normal CT.
 - 3) Service member sustained three or more concussions in past 12 months from any cause.
 - 4) Service member with a documented diagnosis of concussion and has MACE Cognitive Score <25 after 72 hours post-injury.
 - 5) Service member deemed unable to return to duty due to concussion by their chain of command if clinically indicated.
 - 6) Service member with concussion and red flags as discussed above.
 - 7) Service member identified as having persistent concussive symptoms despite standard DTM CPG algorithms in 1A and 2A, and referred to Role III for Comprehensive Concussion Algorithm.
 - 8) Service member may undergo MRI when treating medical officer determines MRI examination needed for clinical concerns not outlined above.
- c. A conscientious provider may responsibly embark on an alternative course of action different from these guidelines when, in the reasonable judgment of the provider, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of the guidelines.

6. References

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Approved by CENTCOM JTTS Director and Deputy
Director and CENTCOM SG

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APPENDIX A

Mandatory Safety Protocols

1. Safety Protocols and Management Principles:

- a. Mandatory safety criteria are met assuring safety to undergo MRI:
 - 1) Safety Officer will be appointed at all sites with MRI capability to ensure proper procedures are in effect, enforced and updated regularly. See document, 'Prevention of "Mission Effect" Accidents, Safety Instructions, April 2011', Exhibit A.
 - 2) Any candidate for MRI will be screened negative by a provider for possible ferromagnetic fragments as per: 1) Procedures Review for MRI Screening and Safety, Exhibit B; 2) MR Procedure Screening Form for Patients, Exhibit C; and 3) MR Procedure Environment Screening Form for Individuals, Exhibit D. Exhibits B, C, and D are used with permission from Dr. Dave Brody. Individuals cannot have any MRI contraindications as detailed in the Exhibits. Additionally, anyone undergoing MRI must be able to lie still in supine position for duration of scan session, have no severe claustrophobia or limiting pain from other injuries, have no metallic implants, and have no metallic foreign objects.
 - 3) All Service members will be assessed using two standardized procedure and environment screening forms (Exhibit C and D) mentioned above.
 - 4) Any and all medical records and radiographs available will be reviewed for possible contraindication to undergoing MRI.
 - 5) Every MRI order will be reviewed by radiologist on staff to rule out safety concerns and add/modify the imaging protocol to obtain most relevant image acquisition.
 - 6) Patients will undergo procedure of removing all clothing, electronics, ID tags or badges, jewelry, hair pins, etc. prior to undergoing MRI study. They will don MR compatible gown to wear during scan and their items will be secured during study. For inpatients requiring medical monitoring during MRI study, a nurse or PA from the floor will remain with the patient during the imaging. Monitoring devices from the floor are switched out for MR compatible components so monitoring can be continuous throughout the scan.
 - 7) A ferrous wand will also be used to rule out the presence of iron materials. A thorough physical exam will be performed by a trained provider prior to MRI, and any entry wounds will be noted. The MR technologist wands the entire patient including any possible entry wound and also head, neck, chest, abdomen, and pelvis, arms, and legs regardless of body part to be examined prior to MRI scanning. Together, this process will ensure that every vital structure is assessed for metallic objects in every patient prior to imaging. In addition, plain x-rays of the appropriate body parts will be requested or reviewed if they have already been performed before MRI scanning.
- b. Exhibits:

1) Exhibit A: **Prevention of “Missile Effect” Accidents: SAFETY INSTRUCTIONS, April 2011**

Prevention of "Missile Effect" Accidents: SAFETY INSTRUCTIONS, April 2011 – Page 1 of 2

The "missile effect" refers to the capability of the fringe field component of the static magnetic field of an MR system to attract a ferromagnetic object, drawing it rapidly into the scanner by considerable force. Obviously, the missile effect can pose a significant risk to the patient inside the MR system and/or anyone who is in the path of the projectile. Furthermore, considerable damage to the MR system may result due to the impact of ferromagnetic object.

Therefore, a strict policy should be established by the MR facility to detect metallic objects prior to allowing individuals or patients to enter the MR environment in order to avoid accidents and potential injuries related to the missile effect. In addition, to guard against accidents from metallic projectiles, the immediate area around the MR system should be clearly demarcated, labeled with appropriate warning or danger signs, and secured by trained staff aware of proper MR safety procedures.

For patients preparing to undergo MR procedures, all metallic personal belongings (i.e., hearing aids, analogue watches, jewelry, etc.) and devices must be removed as well as clothing items that have metallic fasteners or other metallic components (e.g., clothing with metallic threads). The most effective means of preventing a ferromagnetic object from inadvertently becoming a missile is to require the patient to wear a gown without pockets.

Nonambulatory patients must only be allowed to enter the area of the MR system using a nonferromagnetic wheelchair or nonferromagnetic gurney. Wheelchairs and gurneys should also be inspected for the presence of a ferromagnetic oxygen tank or other similar components or accessories before allowing the patient into the MR setting. Fortunately, there are several commercially available, MR-safe or MR-compatible devices that may be used to transport and support patients to and from the MR system room.

Any individual accompanying the patient must be required to remove all metallic objects before entering the MR area and should undergo a careful and thorough screening procedure (need to complete: “Magnetic Resonance (MR) Procedure Screening Form for Patients” and “Magnetic Resonance (MR) Environment Screening Form for Individuals”). All hospital and outside personnel that may need to enter the MR environment periodically or in response to an emergency (e.g., custodial staff, maintenance workers, housekeeping staff, bioengineers, nurses, security officers, fire fighters etc.) should be educated about the potential hazards associated with the magnetic fringe field of the MR system. These individuals should, likewise, be instructed to remove metal objects before entering the MR environment, especially the MR system room in order to prevent missile-related accidents.

Many serious incidents have occurred when individuals, who were unaware of the powers of the fringe field, entered the MR environment with items such as oxygen tanks, wheel chairs, monitors, and other similar ferromagnetic objects. In July 2001, a fatal accident, widely reported in the news media, illustrated the extreme importance of careful attention to ferromagnetic objects that may pose hazards in the MR environment. According to several newspaper reports, a young patient suffered a blow to the head from a ferromagnetic oxygen tank that became a projectile in the presence of a 1.5-Tesla MR system.

While MR safety guidelines and procedures are well known, accidents related to the missile effect continue to occur. Guidelines and recommendations for preventing these hazards are presented in **Table 1**.

Table 1. Guidelines and recommendations for preventing accidents and hazards related to the missile effect in the MR environment.*

- (1) A safety officer or other person responsible for ensuring that proper procedures are in effect, enforced, and updated will be assigned by the Commander or his designee to ensure safety in the MR environment.
- (2) There will be adherence and routine reviews of MRI safety policies and procedures, and measure to assess the level of compliance by all staff members.

Prevention of "Missile Effect" Accidents: SAFETY INSTRUCTIONS, APRIL 2011 – Page 2 of 2

- (3) All MRI staff, along with other personnel who would have an opportunity or need to enter the MR environment (e.g., transport personnel, security officers, housekeeping staff, maintenance workers, health care staff assisting in MRI suite, etc.) will undergo formal training on MRI safety. This will be done and documented especially for new employees and repeated on a regular basis (i.e., yearly).
- (4) Safety officer for MRI will understand and emphasize to all personnel that the static magnetic field of the MR system is always ON and will instruct all personnel to treat the MR environment accordingly.
- (5) All MRI staffing will not allow equipment and devices containing ferromagnetic components into the MR environment, unless they have been tested and labeled as MR safe.
- (6) All MRI staff will adhere to any restrictions provided by suppliers regarding the use of MR-safe and/or MR-compatible equipment and devices in the MR environment. A label of MR safe means that the device, when used in the MR environment, has been demonstrated to present no additional risk to the patient or other individuals, but may affect the quality of diagnostic information (CDRH Magnetic Resonance Working Group 1997). MR-compatible equipment, on the other hand, is not only MR safe, but also can be used in the MR environment with no significant effect on its operation or on the quality of diagnostic information.
- (7) Safety officer or other designated personnel will maintain a list of MR-safe and MR-compatible equipment, including restrictions for use. This list should be kept in every MR center by the MR safety officer.
- (8) MRI staff will only bring non-ambulatory patients into the MR environment using a nonmagnetic wheelchair or gurney. They will also ensure that no oxygen tanks, sandbags with metal shot, or other ferromagnetic objects are concealed under blankets or sheets or stowed away on the transport equipment. Any questions or concerns will be addressed with safety officer.
- (9) Safety officer or other designated personnel will ensure that IV poles accompanying the patient into the MR environment are non-ferromagnetic.
- (10) MRI staff will carefully screen all individuals and patients entering the MR environment for magnetic objects in their bodies (e.g., implants, bullets, shrapnel), on their bodies (e.g., hair pins, brassieres, buttons, zippers, jewelry), or attached to their bodies (e.g., body piercing jewelry). Individuals entering MRI environment will have Magnetic objects on or attached to the bodies of patients, family members, or staff members should be removed, if feasible, before the individuals enter the MR environment.
- (11) Have patients wear hospital gowns without pockets and metallic fasteners for MR procedures. Patients' regular clothing can contain magnetic objects or threads that may pose a hazard in the MR environment.

[*From ECRI Report, 2001, and Shellock FG]

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2) Exhibit B: **Procedures Review for MRI Screening and Safety**

Procedures for MRI Screening and Safety (LRMC Form, used with permission by Dr. D. Brody)

1. All patients are required to fill out an MRI screening forms for patient and environment. This is reviewed by an MRI technologist trained in identifying contraindications and safety concerns for MR.
2. All medical records are reviewed if there is question of possible contra-indication.
3. Radiographs acquired at facility or available from other facilities are reviewed for possible metal fragments/foreign bodies.
4. Every MRI order placed by provider is reviewed by a Radiologist on staff to rule out safety concerns and add/modify the imaging protocol to obtain most relevant image acquisitions for the diagnosis.
5. Just prior to the MRI scan, patients are instructed to remove all clothing, electronics, ID badges, jewelry, hair pins, etc. They are given an MR compatible gown to wear during the MRI scan and their items are secured during performance of the study.
6. For inpatients requiring medical monitoring during the MRI scan, a nurse or PA from the floor remains with the patient during the imaging procedure. Monitoring devices from the floor are switched out for MR compatible components so that monitoring will be continuous throughout the scan.
7. A ferrous wand is also used to rule out the presence of iron materials. The MR technologist wands the entire patient regardless of body part that will be scanned.
8. Windows allow the MRI technologist to watch the patient throughout the scan session from the console room to ensure the patient is not showing signs of distress or discomfort.

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3) Exhibit C: Magnetic Resonance (MR) Procedure Screening Form for Patients

Magnetic Resonance (MR) Procedure Screening Form for Patients – Page 1 of 3

Date ____/____/____ Patient Number _____

Name _____ Age _____ Height _____ Weight _____

Last Name, First Name, Middle Initial

Date of Birth ____/____/____ Male ☐ Female ☐ Body Part to be Examined _____

Month / Day / Year

Address _____ Telephone (home) (____) ____ - _____

City _____ Telephone (work) (____) ____ - _____

State _____ Zip Code _____

Reason for MRI and/or Symptoms _____

Referring Physician _____ Telephone (____) ____ - _____

1. Have you had prior surgery or an operation (e.g., arthroscopy, endoscopy, etc.) of any kind? ☐ No ☐ Yes

If yes, please indicate the date and type of surgery:

Date ____/____/____ Type of surgery _____

Date ____/____/____ Type of surgery _____

2. Have you had a prior diagnostic imaging study or examination (MRI, CT, Ultrasound, X-ray, etc.)? ☐ No ☐ Yes

If yes, please list: Body part, Date, and Facility

MRI _____ Date ____/____/____ Facility _____

CT/CAT Scan _____ Date ____/____/____ Facility _____

X-Ray _____ Date ____/____/____ Facility _____

Ultrasound _____ Date ____/____/____ Facility _____

Nuclear Medicine _____ Date ____/____/____ Facility _____

Other _____ Date ____/____/____ Facility _____

3. Have you experienced any problem related to a previous MRI examination or MR procedure? ☐ No ☐ Yes

If yes, please describe: _____

4. Have you had an injury to the eye involving a metallic object or fragment (e.g., metallic slivers, shavings, foreign body, etc.)? ☐ No ☐ Yes

If yes, please describe: _____

5. Have you ever been injured by a metallic object or foreign body (e.g., BB, bullet, shrapnel, etc.)? ☐ No ☐ Yes

If yes, please describe: _____

6. Are you currently taking or have you recently taken any medication or drug? ☐ No ☐ Yes

If yes, please list: _____

7. Are you allergic to any medication? ☐ No ☐ Yes

If yes, please list: _____

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8. Do you have a history of asthma, allergic reaction, respiratory disease, or reaction to a contrast medium or dye used for an MRI, CT, or X-ray examination? ☐ No ☐ Yes

9. Do you have anemia or any disease(s) that affects your blood, a history of renal (kidney) disease, renal (kidney) failure, renal (kidney) transplant, high blood pressure (hypertension), liver (hepatic) disease, a history of diabetes, or seizures?
☐ No ☐ Yes

If yes, please describe: _____

For female patients:

10. Date of last menstrual period: ____/____/____ Post menopausal? ☐ No ☐ Yes

11. Are you pregnant or experiencing a late menstrual period? ☐ No ☐ Yes

12. Are you taking oral contraceptives or receiving hormonal treatment? ☐ No ☐ Yes

13. Are you taking any type of fertility medication or having fertility treatments? ☐ No ☐ Yes

If yes, please describe: _____

14. Are you currently breastfeeding? ☐ No ☐ Yes

Please indicate if you have any of the following:

☐ Yes ☐ No Aneurysm clip(s)

☐ Yes ☐ No Cardiac pacemaker

☐ Yes ☐ No Implanted cardioverter defibrillator (ICD)

☐ Yes ☐ No Electronic implant or device

☐ Yes ☐ No Magnetically-activated implant or device

☐ Yes ☐ No Neurostimulation system

☐ Yes ☐ No Spinal cord stimulator

☐ Yes ☐ No Internal electrodes or wires

☐ Yes ☐ No Bone growth/bone fusion stimulator

☐ Yes ☐ No Cochlear, otologic, or other ear implant

☐ Yes ☐ No Insulin or other infusion pump

☐ Yes ☐ No Implanted drug infusion device

☐ Yes ☐ No Any type of prosthesis (eye, penile, etc.)

☐ Yes ☐ No Heart valve prosthesis

☐ Yes ☐ No Eyelid spring or wire

☐ Yes ☐ No Artificial or prosthetic limb

☐ Yes ☐ No Metallic stent, filter, or coil

☐ Yes ☐ No Shunt (spinal or intraventricular)

☐ Yes ☐ No Vascular access port and/or catheter

☐ Yes ☐ No Radiation seeds or implants

☐ Yes ☐ No Swan-Ganz or thermodilution catheter

☐ Yes ☐ No Medication patch (Nicotine, Nitroglycerine)

☐ Yes ☐ No Any metallic fragment or foreign body

☐ Yes ☐ No Wire mesh implant

☐ Yes ☐ No Tissue expander (e.g., breast)

☐ Yes ☐ No Surgical staples, clips, or metallic sutures

☐ Yes ☐ No Joint replacement (hip, knee, etc.)

☐ Yes ☐ No Bone/joint pin, screw, nail, wire, plate, etc.

☐ Yes ☐ No IUD, diaphragm, or pessary

☐ Yes ☐ No Dentures or partial plates

☐ Yes ☐ No Tattoo or permanent makeup

☐ Yes ☐ No Body piercing jewelry

☐ Yes ☐ No Hearing aid

(Remove before entering MR system room)

☐ Yes ☐ No Other implant _____

☐ Yes ☐ No Breathing problem or motion disorder

☐ Yes ☐ No Claustrophobia

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Before entering the MR environment or MR system room, you must remove all metallic objects including hearing aids, dentures, partial plates, keys, beeper, cell phone, eyeglasses, hair pins, barrettes, jewelry, body piercing jewelry, watch, safety pins, paperclips, money clip, credit cards, bank cards, magnetic strip cards, coins, pens, pocket knife, nail clipper, tools, clothing with metal fasteners, & clothing with metallic threads.

Please consult the MRI Technologist or Radiologist if you have any question or concern BEFORE you enter the MR system room.

NOTE: You may be advised or required to wear earplugs or other hearing protection during the MR procedure to prevent possible problems or hazards related to acoustic noise.

I attest that the above information is correct to the best of my knowledge. I read and understand the contents of this form and had the opportunity to ask questions regarding the information on this form and regarding the MR procedure that I am about to undergo.

Signature of Person Completing Form: _____ Date ____/____/____
Signature

Form Completed By: ☐ Patient ☐ Relative ☐ Nurse _____
Signature

Print name and Relationship to patient

Form Information Reviewed By: _____
Signature

Print name

☐ MRI Technologist ☐ Nurse ☐ Radiologist ☐ Other _____
Signature

Print name

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4) Exhibit D: MR Procedure Environment Screening Form for Individuals

Magnetic Resonance (MR) Environment Screening Form for Individuals*

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Important Instructions

The MR system has a very strong magnetic field that may be hazardous to individuals entering the MR environment or MR system room if they have certain metallic, electronic, magnetic, or mechanical implants, devices, or objects. Therefore, all individuals are required to fill out this form BEFORE entering the MR environment or MR system room. Be advised, the MR system magnet is ALWAYS on.

WARNING: Certain implants, devices, or objects may be hazardous to you and/or may interfere with the MR procedure (i.e., MRI, MR angiography, functional MRI, MR spectroscopy). Do not enter the MR system room or MR environment if you have any question or concern regarding an implant, device, or object. Consult the MRI Technologist or Radiologist BEFORE entering the MR system room. The MR system magnet is ALWAYS on.

Please mark on the figure(s) below the location of any implant or metal inside of or on your body.

***NOTE:** If you are a patient preparing to undergo an MR examination, you are required to fill out a different form.

Date ____/____/____ Name _____ Age _____
Month / Day / Year Last Name, First Name, Middle Initial

Address _____ Telephone (home) (____) ____ - _____

City _____ Telephone (work) (____) ____ - _____

State _____ Zip Code _____

1. Have you had prior surgery or an operation (e.g., arthroscopy, endoscopy, etc.) of any kind? ☐ No ☐ Yes

If yes, please indicate date and type of surgery: Date ____/____/____ Type of surgery _____

2. Have you had an injury to the eye involving a metallic object (e.g., metallic slivers, foreign body)? ☐ No ☐ Yes

If yes, please describe: _____

3. Have you ever been injured by a metallic object or foreign body (e.g., BB, bullet, shrapnel, etc.)? ☐ No ☐ Yes

If yes, please describe: _____

4. Are you pregnant or suspect that you are pregnant? ☐ No ☐ Yes

WARNING: Certain implants, devices, or objects may be hazardous to you in the MR environment or MR system room. Do not enter the MR environment or MR system room if you have any question or concern regarding an implant, device, or object.

Please indicate if you have any of the following:

☐ Yes ☐ No Aneurysm clip(s)

☐ Yes ☐ No Implanted drug infusion device

☐ Yes ☐ No Cardiac pacemaker

☐ Yes ☐ No Any type of prosthesis or implant

☐ Yes ☐ No Implanted cardioverter defibrillator (ICD)

☐ Yes ☐ No Artificial or prosthetic limb

☐ Yes ☐ No Electronic implant or device

☐ Yes ☐ No Any metallic fragment or foreign body

☐ Yes ☐ No Magnetically-activated implant or device

☐ Yes ☐ No Any external or internal metallic object

☐ Yes ☐ No Neurostimulation system

☐ Yes ☐ No Hearing aid

☐ Yes ☐ No Spinal cord stimulator

☐ Yes ☐ No Other implant _____

☐ Yes ☐ No Cochlear implant or implanted hearing aid

☐ Yes ☐ No Other device _____

☐ Yes ☐ No Insulin or infusion pump

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Remove all metallic objects before entering the MR environment or MR system room including hearing aids, beeper, cell phone, keys, eyeglasses, hair pins, barrettes, jewelry (including body piercing jewelry), watch, safety pins, paperclips, money clip, credit cards, bank cards, magnetic strip cards, coins, pens, pocket knife, nail clipper, steel-toed boots/shoes, and tools. Loose metallic objects are especially prohibited in the MR system room and MR environment.

Please consult the MR Technologist or Radiologist if you have any question or concern BEFORE you enter the MR system room.

I attest that the above information is correct to the best of my knowledge. I have read and understand the entire contents of this form and have had the opportunity to ask questions regarding the information on this form.

Signature of Person Completing Form: _____ Date ____/____/____
Signature

Form Information Reviewed By: _____
Print name Signature

☐ MRI Technologist ☐ Radiologist ☐ Other _____

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APPENDIX B

ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGs

A. Purpose.

The purpose of this Appendix is to ensure an understanding of DoD policy and practice regarding inclusion in CPGs of “off-label” uses of U.S. Food and Drug Administration (FDA)–approved products. This applies to off-label uses with patients who are armed forces members.

B. Background.

Unapproved (i.e., “off-label”) uses of FDA-approved products are extremely common in American medicine and are usually not subject to any special regulations. However, under Federal law, in some circumstances, unapproved uses of approved drugs are subject to FDA regulations governing “investigational new drugs.” These circumstances include such uses as part of clinical trials, and in the military context, command required, unapproved uses. Some command requested unapproved uses may also be subject to special regulations.

C. Additional Information Regarding Off-Label Uses in CPGs.

The inclusion in CPGs of off-label uses is not a clinical trial, nor is it a command request or requirement. Further, it does not imply that the Military Health System requires that use by DoD health care practitioners or considers it to be the “standard of care.” Rather, the inclusion in CPGs of off-label uses is to inform the clinical judgment of the responsible health care practitioner by providing information regarding potential risks and benefits of treatment alternatives. The decision is for the clinical judgment of the responsible health care practitioner within the practitioner-patient relationship.

D. Additional Procedures.

1. Balanced Discussion. Consistent with this purpose, CPG discussions of off-label uses specifically state that they are uses not approved by the FDA. Further, such discussions are balanced in the presentation of appropriate clinical study data, including any such data that suggest caution in the use of the product and specifically including any FDA-issued warnings.

2. Quality Assurance Monitoring. With respect to such off-label uses, DoD procedure is to maintain a regular system of quality assurance monitoring of outcomes and known potential adverse events. For this reason, the importance of accurate clinical records is underscored.

3. Information to Patients. Good clinical practice includes the provision of appropriate information to patients. Each CPG discussing an unusual off-label use will address the issue of information to patients. When practicable, consideration will be given to including in an appendix an appropriate information sheet for distribution to patients, whether before or after use of the product. Information to patients should address in plain language: a) that the use is not approved by the FDA; b) the reasons why a DoD health care practitioner would decide to use the product for this purpose; and c) the potential risks associated with such use.