Accepted Article

**Guidelines for Documentation and Consent for
Non-Clinical, Non-Research MRI in Human Subjects**

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Abstract

Magnetic resonance imaging (MRI) of human subjects is widely performed for clinical and research purposes. Clinical MRI requires a physician order, while research MRI typically requires an approved protocol from a local institutional review board (IRB), as well as informed consent. However, there are several circumstances in which it is appropriate to perform MRI in human subjects, that constitute neither clinical nor research activities. Examples include clinical protocol development, training and teaching, and quality assurance testing. We refer to such activities as non-clinical, non-research MRI. The purpose of this document is to provide principles and guidelines for appropriate and safe use of MRI in human subjects for non-clinical, non-research purposes.

Key Words: magnetic resonance imaging, non-clinical, non-research, regulatory, consent

Introduction

Magnetic Resonance Imaging (MRI) is a noninvasive cross sectional imaging technique that has revolutionized the diagnosis of disease and is commonly used around the world in clinical practice. Further, there are tremendous continued research activities developing new MRI techniques as well as using established MRI methods as part of important research studies including human subjects.

If an MRI study is performed for clinical purposes, a physician order is required and informed consent from the patient is usually not necessary given the high safety protocol and low risk of MRI, relative to many medical procedures. If the activity constitutes research, standard ethical principles typically requires the use of locally approved Institutional Review Board (IRB) or Ethics Board (both hereafter referred to as IRB) protocols for research studies. In particular, most prospective research protocols also involve some form of informed consent.

The appropriate use of an IRB protocol depends highly on the definition of research. Although this definition varies widely, the United States Federal Government defines research as “a systematic investigation, designed to develop or contribute to generalizable knowledge”(1). Other governments and regions of the world have related but different definitions(1-4). It will incumbent upon the reader of these guidelines to familiarize himself or herself with the definition of research that is relevant to their country, and consider this concept in the proposed guidelines.

There are many circumstances where MRI in human subjects (hereafter “volunteers”) falls into a gray zone that constitutes neither research nor clinical imaging. This leads to tremendous uncertainty as to whether these activities should be performed as part of an IRB approved protocol, or whether any form of informed consent is even necessary. We refer to such an activity as “non-clinical, non-research” MRI.

Currently, the use of volunteers in MRI scanners for non-clinical, non-research purposes is highly variable. At many institutions no formal consent is used, while at other institutions IRB research protocols are being used. Although MRI is an exceptionally safe imaging modality, it is not free from all risk. For this reason, guidelines for the appropriate use of non-clinical, non-research MRI scanning and for appropriate use of informed consent are needed. A structured process is needed to ensure safe and appropriate scanning of volunteers, and also to provide the necessary information about the potential risks of MRI to volunteers undergoing non-clinical, non-research MRI.

The purpose of this document is to provide suggested principles and guidelines for appropriate MRI of volunteers for non-clinical, non-research purposes. The essence of these guidelines closely follows the general principles of research and safety pertaining to the appropriate screening of volunteers, informed written consent and all standard safety precautions. It is essential to note that the definitions of research, authority of local IRBs, and the laws and regulations of different countries and regions of the world are highly variable. The guidelines described below may not be applicable in all regions. The intention of this document is not to dictate how such an approach should be performed but rather provide helpful guidelines, should the need for a structured process arise at a specific institution. Any implementation of the guidelines described in this document may benefit from consultation of the local IRB, and must be consistent with local guidelines, laws and customary practices. Please note that the following guidelines have been written on behalf of and approved by the International Society for Magnetic Resonance in Medicine (ISMRM) Safety Committee. A list of Safety Committee members at the time of drafting this document is found in the on-line supporting information.

Definition of Non-Clinical, Non-Research MRI

There are many potential uses of MRI for non-research, non-clinical purposes. While this varies depending on regional regulation, the most common applications of non-clinical, non-research MRI include the following:

1. **Clinical Protocol Development:** When developing new clinical MRI protocols or refining existing clinical MRI protocols, it is often necessary to image volunteers in order to ensure adequate image quality has been achieved, prior to using these protocols in patients for clinical purposes. These protocols are generally comprised of sequences approved by local regulatory bodies for use as defined by the supervising physician.
2. **Training and Teaching:** It is sometimes necessary to image volunteers for the purposes of teaching students and for training operators on the safe and effective use of MRI systems.
3. **Quality Assurance / Quality Improvement:** Testing of existing, repaired or new equipment occasionally requires testing in volunteers to evaluate system performance for quality assurance (QA) and quality improvement (QI) purposes. Evaluation may include (but is not limited to) testing of signal-to-noise ratio (SNR) performance, evaluation of image artifacts, and any metric related to the performance of the MRI system.

In addition to the above applications, there may be other appropriate applications for the use of non-clinical, non-research MRI in volunteers. These may vary by site and by region, and depend on the specific needs of a particular institution. It is important to note, however, that establishing and implementing a research MRI protocol using volunteers, prior to embarking on a research protocol with patients, does not constitute a non-clinical, non-research MRI activity. A separate IRB protocol may be required, if the overall activity is related to research.

Guidelines for Non-Clinical, Non-Research MRI

The following guidelines aim to describe the basic principles and suggested requirements for implementing a careful and orderly process for institutions that wish to implement processes for non-clinical, non-research MRI scanning activities. The following guidelines attempt to provide helpful suggestions to ensure safe MRI practices, and to protect volunteers by following accepted principles of informed consent.

1. The use of volunteers for the purposes of clinical protocol development, training and teaching, and quality assurance testing should be minimized wherever possible. The use of phantoms is advised whenever possible. However, there are currently no phantoms that adequately mimic all the physiological processes that affect an MRI examination, including human anatomy, physiological activity (including that needed for ECG signal and respiratory gating), body composition and MRI relaxation parameters, and other important features that may impact an MRI acquisition, such as ECG signals and respiratory gating. It is recognized therefore that in many circumstances that MRI in volunteers is ultimately necessary for testing clinical protocols, training and teaching, and for some quality assurance applications.
2. It is recommended that sites contact their local IRB, prior to implementing a non-clinical, non-research MRI activity, to ensure that the proposed MRI activities in human subjects do not constitute human subjects research requiring IRB approval. Non-clinical, non-research MRI should never be used to circumvent the appropriate use of IRB approved research protocols.

In general, MRI involving non-approved software and/or hardware (“devices”) requires regulatory and/or local IRB oversight, although this may vary from region to

region. Before using non-approved devices as part of non-clinical, non-research MRI, it is recommended that the site consult with appropriate regulations and the local IRB regarding the use of non-approved devices. For example, in the United States, the Food and Drug Administration (FDA) code of federal regulations (CFR) 812 may provide the necessary guidance(5).

3. In general, all non-clinical, non-research MRI should be performed in healthy adults who can participate in the informed consent process without additional consent required from a parent or guardian. Non-clinical, non-research MRI should not, in any way, replace a medically necessary imaging study.
4. Archiving of images, as well as anonymization and/or deidentification of images should follow local institutional practices similar to those used for research studies. For some applications, such as teaching and training, there may be no need to archive images.
5. Individuals from vulnerable populations(1), which includes children, wards of the state, prisoners, pregnant patients, persons who are mentally disabled or cognitively impaired, or are economically or educationally disadvantaged should be excluded from participation. Further, individuals who are impaired and unable to provide informed consent, including those individuals unable to speak the local language adequately, or have communication impairments should also not participate in non-clinical, non-research MRI activities.
6. All non-clinical, non-research MRI should be performed under the direct supervision of an experienced and qualified (in accordance with local guidelines) MRI operator. In the case of teaching, it may be appropriate for an inexperienced MRI operator to perform the examination, but only under direct supervision of an experienced and qualified operator.

7. A major purpose of developing guidelines for non-clinical, non-research MRI is to ensure that all volunteers undergo appropriate MRI safety screening. MRI safety screening should be performed at a level equivalent to that used for research and/or clinical purposes. As there is no benefit to the volunteer, any concern whatsoever about scanning a volunteer with a contraindicated implant or other questionable contraindication (eg. claustrophobia) should exclude the volunteer from participating. Furthermore, if it were necessary to perform involved procedures such as radiographs to exclude orbital metallic fragments, for example, the volunteer should not undergo non-clinical, non-research MRI.
8. Documentation of appropriate MRI safety screening (eg. signed safety screening forms) is considered essential.
9. The use of contrast agents for the purpose of non-clinical, non-research MRI is highly discouraged. Although gadolinium based contrast agents are considered safe, they are not free from adverse events including allergic reactions and in patients with renal failure, nephrogenic systemic fibrosis (NSF). However, it is recognized that there may be rare and unforeseen circumstances where the use of a contrast agent is needed for an appropriate non-clinical, non-research MRI activity that is not considered research and therefore, is inappropriate to use under an IRB approved protocol. This determination should be made in conjunction with the local IRB, if possible. Should contrast agents be used for non-clinical, non-research MRI, all standard risks of contrast agents, including allergic reactions, NSF, and other known risks, should be included in the consent form, similar to that listed in an IRB approved consent form for the use of contrast enhanced MRI for research purposes. All standard institutional procedures for the safe use of

contrast, including the availability of appropriate equipment, drugs and trained individual(s) needed to treat contrast reactions should be followed. Finally, contrast agents are drugs, and like any drug, the administration of a contrast agent always requires prescription and oversight from a licensed physician.

Recently, there have been several reports describing increased signal with T1 weighted imaging in the deep nuclei of the brain in patients receiving multiple doses of gadolinium based contrast agents(6-9). This imaging observation has raised concern for the possibility of toxicity related to cumulative gadolinium deposition. However, no paired data demonstrating any adverse biological or clinical outcomes have been reported, despite hundreds of millions of administered doses. As there are no known risks related to gadolinium deposition, no specific recommendations regarding informed consent and gadolinium deposition can be made by the ISMRM at this time. Should any adverse biological or clinical effects related to gadolinium deposition be discovered subsequent to this publication, it may be appropriate to include these risks as part of the consent process.

10. Use of non-clinical, non-research scanning should never be performed for any medical purpose. It should be made clear to volunteers that this MRI activity should never be used to replace clinical imaging. Volunteers who are symptomatic or have concerns of underlying disease should consult their physician.

11. Careful consideration should be made to whether to scan employees or trainees within your institution or volunteers from outside the institution. It may be preferable to recruit volunteers who have a working knowledge of MRI safety and the local MRI environment, in order to facilitate the safest possible scanning activity. There may also be

important implications related to workers' compensation and, if needed, appropriate waivers of liability may be necessary within the consent form. Consultation with the appropriate departmental human resources team is encouraged, to ensure that non-clinical, non-research policies are consistent with institutional policies. If employees or trainees are recruited, a supervisor with an authority relationship over volunteers should never be involved in the recruitment of volunteers. It is recommended that a standardized approach for approval of employee participation in non-clinical, non-research MRI be instituted.

Should volunteers who are not employees of the institution be recruited, standard recruiting mechanisms (eg. billboards, emails, etc) such as those used by the IRB may be appropriate based on local institutional practices. Any process that introduces an element of coercion, such as a status relationship or excessive compensation should be avoided. In general it is recommended that minimal compensation, if any, to compensate subjects for their time and expenses (e.g. travel, parking) should be used.

12. Oversight of non-clinical, non-research MRI activities by an appropriate institutional oversight committee, such as an MRI Safety Committee or a dedicated "Non-Clinical, Non-Research MRI Committee" is highly recommended. Similar to an IRB committee, this committee should have experts with experience and training in the principles of human subjects research. Guidance and oversight by a professional with expertise in MRI safety, perhaps as a member of the oversight committee, is also recommended. The oversight committee should appoint one or more qualified individuals who are authorized to approve non-clinical, non-research imaging activities. Finally, in challenging situations, escalation to broader institutional oversight such as the institutional Safety Committee or Risk Management may be necessary. It is incumbent upon the oversight committee to

identify and understand the appropriate institutional pathway(s) should escalation be necessary, prior to implementing local non-clinical, non-research guidelines.

The above list of suggestions provides the basic framework for performing non-clinical, non-research MRI scanning in human subjects. It is recognized that institutional guidelines and regional differences in laws and other regulations supersede all of the above guidelines. If appropriate for your local institution, the above guidelines may provide helpful suggestions for providing an organized process and framework on the appropriate non-clinical, non-research use of MRI in human subjects. In this way, the safe and appropriately documented use of this MRI activity can be performed.

Informed Consent

Informed consent for non-clinical, non-research MRI should be performed to the same standards as performed for research studies. Key elements of informed consent, as listed below, should be included in the consent process. It is also highly recommended that signed informed consent, to document the consent process, is performed. Furthermore, all individuals involved in the consent procedure for non-clinical, non-research MRI activities should have undergone standard research training and certification. For example, standard CITI (Collaborative Institutional Training Initiative) and HIPPA (Health Insurance Portability and Accountability Act) training is recommended for those individuals performing non-clinical, non-research MRI in the United States

All of the basic elements of informed consent, similar to that required in research protocol should be captured in the consent form. The specific elements of informed consent may vary from region to region. One suggestion is to begin with an existing IRB approved consent form and modify it appropriately to suit the scanning activities for non-clinical, non-research

purposes. A new MRI safety screening form and informed consent should be performed every time a volunteer enters the MRI environment for non-clinical, non-research MRI. In circumstances where the volunteer is an employee and an advanced MRI operator (e.g. MRI technologist / radiographer) with an existing safety screening form on file, other safety screening procedures that ensure rigorous MRI safety screening may be adopted. Note that knowledgeable operators may have pre-existing conditions that are acceptable as an MRI operator, but not as a volunteer (e.g. MR conditional device, or medication that interferes with the thermoregulatory system).

When seeking informed consent for research, there are several key elements that should be included in the consent process. Based on widely accepted principles of informed consent⁽¹⁰⁾, we advise that the following basic elements of informed consent used for research should also apply to volunteers for non-clinical, non-research MRI.

1. A statement that explains the purposes of the MRI activity, the expected duration of the imaging session, and a description of the procedures that will be followed.
2. A description of any foreseeable risks or discomfort to the subject should also be included. This includes physical or psychological effects, which for MRI may include:
 - a. Claustrophobia
 - b. Skin burns
 - c. Risk of projectiles
 - d. Nerve stimulation
 - e. Heating
 - f. Acoustic noise
 - g. Risk of disclosing personal medical information to those who may see the images

- h. Risk of discovery of a finding of uncertain medical significance
 - i. Risks of contrast agents, if used
- 3. An explicit explanation that there is no direct benefit to the volunteer, although there may be benefit to future patients by establishing and improving clinical protocols, teaching of MRI operators and through quality assurance and quality improvement of the medical practice.
- 4. A statement regarding whether or not an expert interpreting physician will review images for incidental findings, should be included (please see next section for further details regarding incidental findings).
- 5. If images will undergo a formal review, the potential consequence of identifying findings of unknown clinical significance and potential psychological and health consequences, as well as potential consequences for insurability for healthcare should also be included as a potential risk.
- 6. A statement describing the extent, if any, to which confidentiality of images and any identifying information will be maintained.
- 7. A statement regarding compensation, if any, and/or medical treatments that are available should injury occur as part of this activity. All statements must follow local laws and regulations. It should be noted that the sample consent forms provided in the on-line supporting information are from the USA.
- 8. Information on an institutional contact for any questions that the volunteer may have related to the scanning activity. The specific choice of institutional contact listed on the consent form should be based on the same approach taken for local IRB protocols.

9. A statement that participation in this activity is voluntary and that refusal to participate will involve no penalty or other loss of benefits to which the subject would be otherwise entitled. Volunteers are permitted to withdraw at any time without penalty.

Incidental Imaging Findings

Incidental findings in non-clinical research activities present an unusual challenge. There is a difficult balance weighing the potential benefits such as a life-saving diagnosis of an unsuspected abnormality versus the potential harm created by the anxiety of a finding of uncertain significance and potential implications for employment and insurability. There are no clear consensus approaches for managing incidental imaging findings in the context of research related imaging, and it is recognized that there remains a general ‘... lack of evidence on which to base practice ... on the balance of harm versus benefit in telling research participants about findings ...’.(11). Formalized review of non-clinical, non-research incidental findings may also place an undue burden on sites to find an available licensed physician who is willing to perform formal image reviews(11, 12).

Despite these challenges and lack of evidence, guidance on the development of specific policies and procedures for managing incidental findings are becoming increasingly available(11-13). For example, Thorogood et al propose that feedback policies for incidental findings should describe procedures for determining which data (if any) should warrant review, evaluating incidental findings, re-identifying subjects with findings discovered on anonymized image data, and contacting subjects with incidental findings(13).

In general, we recommend that no formal image review be performed for non-research, non-clinical MRI, so long as this is disclosed in the consent form. This approach may help avoid potential abuse by volunteers seeking MRI as a surrogate for a clinically necessary MRI exam. It should be noted, however, that at some institutions, IRB protocols require review of certain

research MRI studies by board-certified radiologist or other clinical. This practice varies between specific IRB protocols, institutions, and regions. The local IRB may be helpful to provide guidance on this issue, although it should be noted that oversight of the IRB applies only to human subjects research activities, and does not apply to non-clinical, non-research MRI activities.

As discussed above, any guidelines that choose to review images for incidental findings should include a statement in the consent form describing the process for informing the subject and/or his/her physician..

Conclusions

In conclusion, the principles and guidelines described in this document are aimed at providing a useful framework and process for appropriate and safe non-clinical, non-research MRI in human volunteers. Without a physician order and without an approved IRB protocol, many institutions do not have well developed processes including elements of informed consent that ensure that standard MRI safety practices, and the principles of beneficence and informed consent are adhered to. We believe that this document provides a reasonable approach to provide an orderly process for human scanning in the gray zone between clinical and research MRI activities.

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**Volunteer Consent and Waiver of Liability
for
Participating in a Non-Research, Non-Clinical, Magnetic Resonance (MR) Exam**

This is an important form. Please read it carefully. It tells you what you need to know about participating in a non-research, non-clinical, MR exam. If you agree to participate in a non-research, non-clinical, MR exam, you need to sign this form. Your signature means that you have been told about the MR exam, and the risks, and that you voluntarily agree to participate.

Purpose of Non-Research, Non Clinical, MR Exams:

Examples of instances when MR exams may be necessary for non-research and non-clinical purposes may include, but are not limited to the following:

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

Requirements for Participation:

In order to participate in non-research and non-clinical MR exams, volunteers must:

1. be at least 18 years old.
2. not be pregnant, or think they may be pregnant.
3. complete a standard [name of institution] MRI Safety Screening form prior to each MR exam and have no contraindications for undergoing an MR exam.
4. read and sign this form prior to each MR exam.

The Non-Research, Non-Clinical, MR Exam:

Prior to the MR exam, you will be asked to provide an accurate estimation of your weight, which is information collected from everyone who participates in an MR exam.

The MR exam will feel the same as a standard clinical MR exam. You will be placed in the center of a large doughnut-shaped magnet. The MR machine produces a magnetic field that passes through your body without disturbing any of its parts. Radio signals will be sent into your body. A small proportion of the water in your body will send back radio signals that the machine receives. The MR machine uses a computer to determine where these radio signals came from to make a picture showing us what the inside of your body looks like.

You may be required to wear a hospital gown during the MR exam. A changing room will be provided and your privacy will be respected at all times. A pulse oximeter or ECG leads also may be attached to your body, to painlessly provide a tracing of your heart rate during the MR exam. During a scan, the MRI scanner will make a tapping or "chirping" noise. Earplugs or headphones will be provided to minimize any potential discomfort.

For this MR exam, you may be given an injection of an FDA-approved contrast agent. A contrast agent is a special medication that causes blood vessels and certain tissues to appear brighter on the MR images. Prior to the start of the MR exam, a small catheter ("IV") will be placed in one of your veins, usually in your arm. During the MR exam, you will receive one or more injection(s) of a contrast agent through this catheter. The maximum dose that will be used in this MR exam will not be higher than the maximum dose used for clinical purposes.

The MR exam will consist of several MR scans. Individual scans last from a few seconds to as long as several minutes. You will need to lie still during the individual scans. You may be asked to hold your breath during some scans. The MR exam may last up to 90 minutes.

The MR exam will be performed at the [name of imaging facility].

You will not be paid for participating in this MR exam. Neither you nor your insurance company will be billed for the MRI scans acquired, or any contrast agent administered, during this MR exam.

Risks:

Although no known ill effects have been directly attributed to exposure to the radio waves or the strong magnetic field used in MR, it is not safe to scan people with certain types of metallic implants in their bodies. In order to determine if it is safe for you to have an MR exam, the person facilitating your exam will ask you a series of questions. It is very important that you answer these questions accurately and thoroughly.

In rare situations, people have reported muscle twitching during fast scans or a sensation of electric shock when they clasp their hands together during fast scans. However, these feelings are not hazardous, and will be mild. To avoid the sensation of electric shock, you should not clasp your hands together during the MR exam.

Occasionally some individuals experience feelings of claustrophobia during an MR exam.

There is a rare potential risk of a skin burn during an MR exam.

If ECG leads are used, these leads may cause minor skin irritation or skin reddening when removed.

If a contrast agent is administered, the agent may cause a headache, nausea, reaction at the injection site, or vasodilatation (temporary widening of a blood vessel). These were the most frequent side effects reported during clinical trials with MRI contrast agents, and they occurred in less than 3% of subjects. Other less-common side effects reported were bad taste in the mouth, skin rash, dizziness, or warm tingling or burning feeling on the skin. Vein puncture can cause bruising, pain, or a rare incidence of infection at the vein puncture site. There is a slight risk of fainting when the catheter is inserted.

Support will be provided to keep you from becoming uncomfortable, and you will be able to stop participating at any time. Using a microphone built into the MR scanner, a technologist will be able to hear you if you need assistance at any time. Please inform the technologist of any discomfort you may experience during the MR exam.

In Case of Injury:

In the event that you are physically injured as a result of participating in this MR exam, emergency care will be immediately available. However, you will be responsible for the charges for the

emergency care and there is no commitment to provide any compensation for any injuries you may obtain unless you are an employee of [name of institution], and you volunteer during work hours, and Worker's Compensation laws state otherwise.

This is NOT a Substitute for a Clinical MR Exam:

The scans that will be performed during this MR exam will not be used to diagnose medical problems. This MR exam should not be used to replace a visit to your primary physician. If you are having physical symptoms that you believe may be related to some disease, you should see your primary physician, who will then direct the order and types of studies required to arrive at a diagnosis. The images from your MR exam will NOT be placed in your medical record and a copy of the images will NOT be provided to you. Furthermore, the images will NOT be submitted for any formal review by a physician.

Possible Discovery of Medical Findings:

Whenever an MR exam is performed, there is the chance of finding something unexpected. **As there will be no formal review of the images, you should not expect to receive any report describing findings, and you should not expect to receive any results, normal or otherwise, written or verbal.**

Sharing of MR Images:

Images obtained during this MR exam may be shared with the manufacturer of the MR system, [names of any relevant companies] or other institutions or companies so that they may i) provide us feedback and help us improve image quality, ii) assist us with developing hardware or software, iii) assist us with analyzing or evaluating the images, or iv) use the results of the MR exam to help them make products. Any images that are shared will not contain your name or any of your personal information.

Participation is Voluntary:

Your participation in this MR exam is entirely voluntary. If you are an employee of [name of institution], you should not agree to participate in an MR exam during work hours unless you have received permission from your supervisor. You may refuse to participate or you may stop participating at any time without affecting your present or future medical care at [name of institution], You do not have to sign this form and you may refuse to do so. If you refuse to sign the form, however, you cannot participate in this MR exam.

Contact Information:

If you have questions about participation in this MR exam, please contact [institutional contact, eg. Medical Director of MRI] at [phone number, other contact information] if your MR exam was performed at [name of imaging facility].

Consent and Waiver of Liability:

I have read this Consent and Waiver of Liability form describing the procedures and risks associated with participating in a non-research, non-clinical, MR exam. I have had a chance to ask questions, and I have received answers to my questions. By signing below, I express my understanding and intent to participate in a non-research, non-clinical, MR exam. To the extent permitted by law, I release [name of institution], and their officers, employees, agents, affiliates and assigns ("Released Parties") from liability, costs and damages that I may incur as a result of my participation in the non-research, non-clinical, MR exam. The above stated waiver does not apply to any Worker's Compensation claim or to recklessness or intentional misconduct by the Released Parties.

You will receive a copy of this form after signing it.

Signature of Volunteer

Date

Printed Name of Volunteer

For qualified MR personnel who are [name of institution] employees, only:

Do you have an accurate MRI Safety Screening form on file? ☐ yes ☐ no

If no, a new MRI Safety Screening form must be completed.

To be completed by authorized person obtaining this consent:

Printed Name of Authorized Person Obtaining Consent

Brief Description of MRI Scanning Activity: _____

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Author/s:

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Title:

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