MR#: (Assigned by Research MRI Safety Office)

Principal Investigator (PI): Click or tap here to enter text.

Department: Click or tap here to enter text.

Contact Person: Click or tap here to enter text.

Contact Person Phone Number: Click or tap here to enter text.

Contact Person Email: Click or tap here to enter text.

Protocol Title: Click or tap here to enter text.

**NOTE: If your study has a related MCW/FH Institutional Review Board Human Project (PRO) DO NOT COMPLETE THIS FORM. By indicating the use of MRI within the PRO, the study is automatically routed to the Research MRI Safety Committee for review.**

**DO NOT COMPLETE THIS FORM IF:**

* **All MRI procedures in the protocol are considered standard of care**
* **All MRI procedures in the protocol are performed at Froedtert Hospital Radiology *and* billed to patient/insurance as routine care cost**

***Instructions:***

1. ***Add information in areas designated by “Insert text here”***
2. ***Check the appropriate boxes that apply to the study***
3. ***Submit completed application to*** [***MRIresearch@mcw.edu***](mailto:MRIresearch@mcw.edu)

**Section 1 – MR Imaging in a Clinical Setting**

**(Complete this section if the research data being collected is acquired during a clinical MRI scan)**

1. Identify the MRI system(s) that will be used:

*\*Please ensure that prior authorization to use the below MRI systems is granted before any research is conducted. Research MRI Safety Committee approval does not grant approval to use the MRI equipment.*

Children’s Hospital of Wisconsin Clinical MRI System(s)

Center for Imaging Research clinic based MRI System(s) (e.g., 3T scanner in Froedtert Pavilion)

Froedtert Center for Diagnostic Imaging Outpatient MRI System(s)

Froedtert Hospital Network Clinical MRI System(s)

Other

If other, click here to provide location of the MRI system

1. Who will be operating the MRI scanner?

A Registered MR Technologist

Another trained individual

If another trained individual, click here to identify and provide qualifications.

1. Clarify how the research MRI Imaging, as it relates to an MRI exam, deviates from participant’s standard of care.

Constitutes no change from the “Standard of Care”.

Includes more frequent scanning than the “Standard of Care” exam.

Increases the duration of the “Standard of Care” exam.

Purpose of imaging is non-clinical

Other deviations.

If other, click here to describe deviations

**Section 2 – MR Imaging in a Non-Clinical Setting**

(Complete this section if you are proposing to use one of the research scanners managed by the Center for Imaging Research (CIR))

1. Where are you proposing to conduct your research MR Imaging?

*\*For authorization to use the MRI system(s), please contact the Center for Imaging Research.*

Daniel M. Soref Imaging Research Facility MRI System(s) (e.g., 7T/3T Priemer)

Other

If other, click here to provide location of the MRI system

1. Who will be operating the MRI scanner?

A Registered MR Technologist

Another trained individual

If another trained individual, click here to identify and provide qualifications

**Section 3 – MRI Scanning for Research Purposes Using Non-Significant Risk (NSR) Investigational Devices**

1. Identify the Name of the MRI device:

Click here to identify device

1. Identify if any of the following scanner hardware(s) will be utilized:

Non-FDA approved receive RF Coil

Non-FDA approved transmit RF Coil

Other scanner hardware modifications

None of the above

1. Will the pulse sequences be developed within the vendor environment?

Yes

No

1. Provide details based on the above selections:

Click here to describe

1. Will other study-related equipment be brought into the magnet room?

Yes

No

If yes, click here to describe equipment

**Section 4 – Human Research Population**

1. How will project team members provide support for the following subject populations during the MRI procedure?

*\*If imaging is being performed in a clinical environment with registered technologists and includes standard of care, please simply note that standard clinical practices will be followed, unless the protocol includes a deviation from the standard of care with respect to subject management.*

Minors (0-9 years)

*- In the textbox below, include credentials, training, and/or experience with pediatric imaging of the project team members who will perform screening and/or be present for imaging.*

Minors (10-17 years)

*- In the textbox below, include credentials, training, and/or qualifications of project team members who will perform screening and/or be present for imaging.*

Elderly (age 70 and older)

*- In the textbox below, include credentials, training, and/or qualifications of project team members who will perform screening and/or be present for imaging.*

Individuals with a condition or disease that requires additional support or attention during the scan

*- In the textbox below, include the condition, disease, mobility concerns, and/or issues of cognitive or decisional impairment of the individuals. Also, include the credentials, training and/or qualifications of project team members who will perform screening and/or be present for imaging.*

The above study populations will not be included in MRI procedures

* 1. Describe modifications to the standard screening and imaging support process that will be made for this subject population:

Click here to describe modifications

**Section 5 – Using Gadolinium Based Contrast Media for Research Purposes Only**

1. Will Gadolinium-based contrast media be administered to subjects for research purposes?

Yes

No

* 1. Will the [Gadolinium Use for Research Subject Policy (MR.SOP.4)](https://www.mcw.edu/departments/research-mri-safety/sops) be followed?

Yes

No

If no, click here to describe and justify deviation

* 1. Who will administer the Gadolinium-based contrast media?

Certified MR Technologist

Registered Nurse

Other

If other, click here to identify who will administer

* 1. Describe the response plan for managing any adverse or allergic reaction to the Gadolinium-based contrast media (include descriptions of individuals responsible for implementing the plan).

*\*If imaging is being performed in a clinical environment with registered technologists and includes standard of care, please simply note that standard clinical practices will be followed, unless the protocol includes a deviation from the standard of care with respect to subject management.*

Click here to describe

* 1. Justify the use of Gadolinium-based contrast media for research purposes in both health subject populations and those with a condition or disease.

*\*The inclusion of Gadolinium-based contrast media for research purposes (including the more frequent administration of contrast media) may alter the risk classification of a study due to nephrogenic systemic fibrosis and general Gadolinium retention.*

Click here to describe

* 1. Scanning conducted at a non-clinical location using Gadolinium-based contrast media requires that an MD or DO be present during the scan. Provide the name of the MD or DO who will be present to manage adverse reactions to the contrast agent:

*\*Only answer this question if the MRI scans will be performed in a non-clinical setting.*

Click here to describe

**Principal Investigator Attestation**

I acknowledge responsibility for the conduct of the MRI procedures described in this application:

* I am familiar with the potential hazards in the magnetic environment and agree to full adhere to requirements delineated in this application.
* I have read and understand the MCW research MRI Safety Standard Operating Procedures and agree that they will be followed by study team members.
* I have read and understand the MCW research MRI Safety Scanner Software Modification Policy and agree that they will be followed.
* I agree that as the Principal Investigator, I will have sufficient personnel on-site during scanning session(s) to ensure safe practices.
* I agree that at least two MRI safety trained individuals will be present in the immediate area during scanning session(s).
* I agree that all study team members who enter the magnet room will be compliant with MRI Safety Training requirements.
* I agree that all subjects and items will be screened for safety prior to entering the magnet room.
* I agree that hearing protection will be worn by all research participants who are in the magnet room during scanning.

Principal Investigator Signature

*My signature above indicates that the study team identified below work under my supervision. I certify that prior to initiating work with MRI, all personnel will complete MRI Safety Training as required.*

**Study personnel who will be screening subjects and/or entering the magnetic environment:**

|  |  |  |
| --- | --- | --- |
| **Last, First (Printed)** | **Date** | **Email** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
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