Guidance
Research Use of MRI in Non-Hospital Environment and Application Supplement Form

Notes
Review guidance and complete the supplement form at the end of this document when you intend to conduct research MRI in a non-Children's Wisconsin hospital space. This entire document must be available to the IRB of record. For studies being submitted to the MCW pediatric IRB, upload in Section 52 of the PRO (or Section 98 of an amendment application). Follow submission instructions when an external IRB is serving as the IRB of record.

The Children's Wisconsin hospital environment is well-equipped with tools, techniques, medications, and specialized personnel to make the MRI environment safe for children. When a research study proposes to use an investigational MRI scanner or a scanner not located in Children's Wisconsin hospital space (regular or fMRI) on a Children's Wisconsin patient, there are special considerations that the IRB must take into account for the protection of these subjects. While the device and procedure itself could be deemed no more than minimal risk, the age of subject population and their underlying health status, as well as the location of the MRI device may alter this risk to be considered greater than minimal. The Children's Wisconsin HRPP has identified additional concerns that must be addressed when the IRB reviews a study and additional protections be applied as appropriate. This will be identified during the local context review of each study and it is expected that the determinations be documented (typically in the meeting minutes). Addressing the questions below will help you prepare for scanning outside the Children's Wisconsin hospital space. The local context and IRB review process will take this guidance and PI justifications into consideration. It is possible, depending on the circumstances of the specific study, certain proposed aspects may not be logistically feasible.

Please plan to consult with Children's Wisconsin HRPP (cwhrpp@childrenswi.org) and Children's Wisconsin imaging personnel when planning the scanning logistics.

The IRB should be sensitive to the fact that when the scan is conducted outside the Children's Wisconsin Joint Commission-accredited pediatric hospital environment, emergency procedures may differ based on location. For example, if there is a life-threatening emergency, standard emergency procedures are to call a code and the code team will respond. When the code is called, the subject is removed from the magnet room and is treated in the area outside of the magnet room. The code cart outside the magnet room may not have pediatric equipment and the code team may not have pediatric-specific experience; they will not have Children's Wisconsin-verified pediatric competencies. Depending on the circumstances, 911 may need to be called.

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Locations include:

- Froedtert Pavilion
- Daniel M. Soref Imaging Research Facility
- Research-Specific Imaging Centers

The circumstances specific to the study, patient population, and MRI scanning location can be described by the PI in the questions below for the IRB's consideration.

In order for the IRB of record to consider approving studies utilizing MRI for research in these environments, the following must be addressed:

- For equipment outside of Children's hospital environment, Children's Wisconsin local context and imaging department review are required. The Children's Wisconsin Imaging Department Intake Form must be included with the submission. In addition, the MCW MRI Safety Committee must be informed and have reviewed and approved the proposed MRI use. These studies are not reviewed by the CW MRI Safety Committee.
- Patients younger than 2 will not be permitted in non-clinical scanners.
- The subject's own baseline health status must allow them to undergo the test **without sedation or contrast**. If MRI with sedation is required, this must be done in the CW hospital environment.
- If a child has previous experience with a clinical/routine care MRI, the plan for screening can be described in the supplement form below. If the child does not have MRI experience, videos of the scanning experience, use of a mock scanner, shortened scanning time, distraction tools should be described to reduce the risk of adverse events related to having to lay supine for long periods of time.
- Based on the experience of MRIs performed at Children's Wisconsin and other children's hospitals nationally, children 7 years and under often need sedation to assist them in being still enough to capture diagnostic images. As children become older they will also be able to better understand the instructions provided by the MRI team during a non-sedated scan. To include patients 2-7 years old, the study team will need to present a comprehensive plan to address and mitigate the possible anxiety associated with non-sedated scanning, including but not limited to 1) demonstrated previous non-traumatic experience in a clinical scanner without sedation; or 2) a plan to provide exposure to a mock scanner of similar duration to lessen the likelihood of a traumatic scan experience; 3) availability of appropriately trained research staff to assist with anxiety; and/or 4) use of distraction tools (e.g. MRI safe video headsets).
- In addition to the age considerations, the PI must address in the submission whether to also restrict eligibility to normal healthy patients or those who have mild systemic disease (examples- asymptomatic congenital cardiac disease, well controlled dysrhythmias, asthma without exacerbation, well controlled epilepsy, non-insulin dependent diabetes mellitus, abnormal BMI percentile for age, mild/moderate Obstructive Sleep Apnea, history of oncologic state in remission,

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autism with mild limitations) and whether the subjects are able to understand and follow the instructions provided by the MRI team. If the PI feels these restrictions are not necessary, the rationale must be provided. The subject's own baseline health status (taking into consideration any mental health issues) must allow them to undergo the MRI test and be supine for the duration of the test.

- The PI must have and describe for the IRB the plan for handling medical emergencies that could occur during the MRI in a non-clinical area (see above).
- Subjects must be aware that the MRI is occurring in a Children's Wisconsin Joint Commission-accredited pediatric hospital environment and details must be provided in the consent to describe the emergency response plan.
- Given the increased risk of vertigo, dizziness, metallic taste and nausea reported during movement within 7.0T scanner, use of this scanner in pediatric patients will require additional review.
- If patients must leave the Children's Wisconsin environment for a research MRI somewhere else, this must be described in the application and consent. Inpatients cannot be discharged from the hospital for the purposes of a research MRI.

The informed consent document approved by the IRB must address anything unique about the Children's Wisconsin Joint Commission-accredited pediatric hospital environment, including the possibility of traumatizing a younger child for future clinical or routine care MRI scans. The consent and submission must also address who would be responsible for any costs related to an unanticipated problem that occurs during the research.

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Supplemental Form
The purpose of this form is to provide additional local context information for the CW HRPP and the IRB of record regarding proposed safety measures for research-related MRI procedures involving Children's patients when the MRI takes place outside of the CW hospital clinical scanners. Please include this form with your IRB submission. If the question is already addressed in detail in the submission application or included protocol, you can provide specific page and section references in lieu of written description.

Instructions to the IRB of record: **depending on the age of the subjects and population being targeted, the conduct of MRI scans outside the Children's Wisconsin Joint Commission-accredited pediatric hospital environment may be considered a greater than minimal risk activity. Convened IRB review is strongly encouraged for careful consideration of these risks; Children's Wisconsin HRPP requires documentation in the IRB record that these specific risks have been considered and appropriately minimized. A review of the IRB documentation will be conducted by the Children's Wisconsin HRPP team to ensure this has occurred. If the IRB of record wishes to discuss these considerations, please contact the CW HRPP office: cwhrpp@childrenswi.org.**

Study title: Click here to enter text.

PI: Click here to enter text.

Person completing this form: Click here to enter text. Date: Click here to enter text.

1. Given these considerations, provide rationale to use a non-hospital scanner (cost should not be the primary motivator):	Click here to enter text.
2. List specific scanner(s) and location(s) being proposed:	Click here to enter text.
3. Proposed age range (provide detailed justification if under age 8):	Click here to enter text.
4. Does this population include subjects with a specific disease/ condition? If yes, please describe:	Click here to enter text.
5. What conditions have been excluded from this subject population in order to minimize risk of the MRI?	Click here to enter text.
6. What are the potential risks/complications/hazards for this subject population that could occur during scan? You may need to break down by age group.	Click here to enter text.
7. Describe plans to prevent/minimize the possible hazards (for example, use of a mock scan or describe if some children have previous	Click here to enter text.

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experience in the MRI environment).	
8. What instructions are given to subjects to mitigate possible anxiety-related issues (e.g. panic or flight reaction) during the scan?	Click here to enter text.
9. Describe any distraction tools available (e.g. MRI safe video headsets) to mitigate possible anxiety-related issues:	Click here to enter text.
10. Describe plans to respond to anxiety-related issues should this occur during the scan:	Click here to enter text.
11. Describe the training provided to MRI operators to help them understand the proposed subject population, since this is a non-hospital-based scanner environment:	Click here to enter text.
12. Describe plan for pediatric response procedures in the event of an unanticipated problem (including calling 911) during the scan:	Click here to enter text.
13. If patients must leave the CW hospital environment for a research MRI somewhere else, include here a description of the transportation plan and the language that will be included in the informed consent document (the consent must be clear that subjects will be leaving CW hospital or clinic space):	Click here to enter text.