GUIDANCE: Research MRI

1. **Generally, MRI exams are non-invasive, minimal risk studies that do not use ionizing radiation and are eligible for expedited review by the PPHS. However, certain conditions may elevate from an expedited protocol to full Board review. These include:**
   - **a.** A study requiring careful observation of subjects while undergoing MRI such as use of conscious sedation.
   - **b.** Use of a contrast agent
     - **i.** a. Group II (Gadavist, Dotarem, Prohance, Multihance) or Group III (Eovist) gadolinium agents are preferred. Historical gadolinium preparations using a linear molecules (Group I: Magnevist, Omniscan, Optimark) have been associated with increased risk, most notably nephrogenic systemic fibrosis, so rationale for using any of these discouraged agents should be specifically justified.
       Renal function needs to be assessed before any gadolinium preparation is used for research purposes. Describe how and when the subjects' renal function will be assessed. A minimum eGFR of 30 ml/min/1.73 m^2 is required for contrast administration. A compelling rationale will be needed if lower candidate eGFR threshold will be used or if renal function will not be measured.
   - **c.** Non-approved coils: any use of non-standard coils must 1) address their FDA status and 2) provide documentation from the BMEII Imaging Research Safety Committee indicating the coils have passed safety testing and are approved for use. All non-FDA-approved coils must be reviewed and cleared by the BMEII Research Safety Committee before they can be used on any scanner.[1]

   - **d.** 7 Tesla (7T) MRI: The FDA has determined that 7T scanners are non-significant risk devices.
     - **i.** Most 7T scanners (including the Siemens 7T scanner in Mount Sinai's Hess building on the main campus) remain investigational, since they have not been approved for clinical use or cleared for clinical marketing. For this equipment, the initial review of the study will require review by the full Board.
     - **ii.** For proposals using an approved 7T scanner please submit FDA approval. These will be eligible for expedited review by the PPHS.
   - **e.** Metallic objects screening: If imaging with ionizing radiation (i.e., CT or radiography) is needed to identify retained metallic foreign body(s), full Board review is required along with a submission to Radiation Safety.
     - **i.** If *ad hoc* screening CT or radiography is needed, and this imaging was not disclosed in the initial protocol and consent, an amendment must be submitted to

[1] Software considerations: if you are testing new scanning algorithms that are not FDA approved, confirm the non-FDA approved sequences will respect the specific absorption rate limits established by the manufacturer.

the IRB and Radiation Safety before the screening is performed. This pathway will rarely be approvable in children and in control groups.

2. **What is required if I change from a 3 Tesla to a 7T MRI?**
   This modification will require full Board review if the 7T scanner has not been cleared and approved for use (see above). Additional language will need to be added to the consent document.

3. **What language needs to go into my consent document?** This depends on the scanning protocol, equipment being used, and patient population. **Insert appropriate language passage(s) from the options below** that pertain to the specific study you are conducting.

   General MRI risks and discomforts (use for all field strengths)

   MRI scanning involves the use of a magnet and radio frequency energy. Therefore, patients who have implanted metal devices, such as pacemakers, certain aneurysm clips, or shrapnel or metal in the eye are at risk. You will complete a screening form to identify metals, but if you have any question of metal in the body, you should inform the technologist or investigators before entering the magnet room. If you have metal in your body that you are unable to remove, the safety team will determine whether you will be able to undergo MRI scanning safely. Because of the strong magnetic field associated with the scanner, it is rare, but possible, that a metallic object could fly through the air toward the scanner and hit you. To reduce this risk, everyone in the vicinity of the magnet will remove all metal from their clothing or pockets when in the scanning environment.

   To create images MRI employs radio waves. These waves are not harmful, however, MRI scanners do produce loud noises when these waves are generated. To minimize discomfort, you will be provided with disposable earplugs or headphones that help suppress external noise levels but do not eliminate the noise so that you can have voice communication with the scanner operator. Some individuals may also experience a feeling of claustrophobia (fear of being trapped in a narrow place) during scanning, but the machine may be stopped at any time during the scan upon your request.

   Other risks of MRI that rarely occur include neurostimulation effects, such as muscle twitches and tingling sensations, due to the rapid switching of magnetic fields, and a slight increase in body temperature that may occur in the presence of radio frequency energy. These are very unlikely under current operational guidelines. In the very remote event that the magnet loses its magnetism, helium gas in the magnet will escape. The room is designed with ventilation systems to prevent accumulation of these gases. Should this occur, you will immediately be brought out of the magnet room.

Additional language to use when 7T scanner will be employed

With a non-approved scanner (including Hess 7T scanner): The FDA considers magnetic field strengths up to 8T to pose no more than minimal risk, however the scanner used in this protocol has not specifically been approved for clinical or diagnostic use. No persistent adverse effects have been reported by facilities with magnetic field strengths at 7T. However, some people have reported brief or fleeting dizziness, nausea, or a metallic taste upon being moved into and out of the scanner. These effects typically last less than 10 minutes, and can be minimized by reducing the speed at which the person enters and exits the magnet.

With an approved scanner: The FDA has approved the use of the use of this 7T MRI scanner for clinical and diagnostic use, and considers magnetic field strengths up to 8T to pose no more than minimal risk. No persistent adverse effects have been reported by facilities with magnetic field strengths at 7T. However, some people have reported brief or fleeting dizziness, nausea, or a metallic taste upon being moved into and out of the scanner. These effects typically last less than 10 minutes, and can be minimized by reducing the speed at which the person enter and exits the magnet.

Pregnancy risk (for women of child-bearing potential)

MRI protocols without contrast:

There are no known risks during pregnancy to having an MRI. There may be risks that are unknown. Current FDA guidelines state that safety has not been established for imaging the fetus.

MRI protocols with contrast:

MRI scans done using injected dyes, called contrast agents, are not approved for use in pregnant women. Therefore, a negative pregnancy test will be required before the dye can be used with any woman who can become pregnant.

Gadolinium contrast

For some magnetic resonance imaging (MRI) scans, you may get MRI contrast material (often call “dye” although it has no color). This is given in your vein using a small needle or plastic tube. You may feel local warmth or pain in the area where the dye is injected. Side effects from the contrast may include nausea, vomiting, or headache. Most contrast material

used for MRIs contains gadolinium. Persons with severe kidney insufficiency (kidneys do not work well) or chronic liver disease experiencing kidney insufficiency may develop a severe disease called nephrogenic systemic fibrosis from gadolinium. Nephrogenic systemic fibrosis triggers thickening of the skin, organs and other tissues. The exact cause is unclear, and while this is rare with newer agents, there remains no effective treatment. The MRI contrast material you receive will be given in amounts that have been approved by the FDA. You will not get the MRI contrast material if you have inadequate kidney function, so a blood test may be necessary to determine your kidney function. Serious allergic reactions to contrast that may be life-threatening are very rare.

Gadolinium contrast agents may leave trace deposits in the brain and elsewhere in the body. While there is no evidence that these deposits ultimately affect the health of patients or subjects, the long-term safety of these agents is actively being studied. You will be given the minimum dose necessary to achieve the appropriate quality of images in this protocol.

Sedation

The use of sedatives (something that will help make you calm) may be necessary to minimize any discomfort to you. You can ask your study doctor to write a prescription for this medication. Sedative medications and tranquilizers, like valium, are used to help you remain calm and to lessen any anxiety you may experience. These medications cause drowsiness (a tired feeling) and sometimes sleep. They often also produce short periods of amnesia so that you may not remember some of the events which occur after you are given the medication. The most common side effect is drowsiness, which lasts for some time after the MRI; slow heart rates or allergic reactions. All of these side effects can be treated and in most instances will not cause any permanent injury. You will be closely watched for any side effects when given this medication, and any problems will be quickly treated. Those under influence of sedatives may not drive, so if you need to take a sedative, we ask that you have someone accompany you to the MRI and drive you home.

Incidental Findings (for all scans)

The machine settings used for this special MRI are not chosen to pick up structural changes in the brain, for example: masses or bleeding. However even research MRI scans may reveal unexpected finding(s). Should this occur, the finding(s) will be considered by the appropriate personnel and the PI will inform you if necessary. These possible finding(s) may or may not be significant and may lead to anxiety about your condition and to further work-up by your physician and may result in additional cost to you.