**Required IRB Protocol Language for Studies Involving MRI Procedures**

*This page provides required language for all protocols using MRI research procedures. The safety SOPs articulated here MUST be included in the procedures of the study. Please describe and justify any deviations from this language in your IRB protocol.*

*All consent forms MUST include the following incidental findings language. You can find this language in the document titled “*[*Required Informed Consent Language for Studies Using MRI Procedures*](https://www2.cuny.edu/wp-content/uploads/sites/4/page-assets/research/research-compliance/human-research-protection-program-hrpp/hrpp-policies-procedures/MRI-Consent-Incidental-Finding-Language.pdf)*.”*

1. INFORMED CONSENT FORM>>Confidentiality section:

There is a possibility that the MRI scans taken as part of this research study will show an unexpected abnormality. This is called an "incidental finding." If the researchers suspect an incidental finding they may notify the participant after consulting with a radiologist, who may be provided with the scans but without any identifying information. However, the research staff are not trained medical doctors and may not have the skills to detect incidental findings and/or make diagnoses. Furthermore, the quality and types of MRI images that are taken as part of this study may not be sufficient to make clinical diagnoses. An incidental finding may be meaningless, but the participant may want to talk to a medical professional to find out.  If there is an incidental finding and the participant decides to have further examinations, tests, and/or treatments, the participant and/or the participant’s insurer will be responsible for any costs of such examinations, tests, or treatments.

1. SAFETY SOP - *please insert this language in the Participants>>Screening section in Ideate:*
2. PRESCREENING: Anyone entering the MR environment must be screened for any potential hazard using the MRI safety screening form template ***before*** entering the MR environment.  A written screening form must be completed each time a participant prepares to undergo an MRI scanning session.  If a potential hazard is found (a box marked “yes” on the safety screening form) then written documentation identifying the manufacturer/model and type of hazard (implant, device, etc.) must be obtained or assurance of safety and conditions needs to be verified ***before*** the research subject or other individual is brought into the MR environment.  Assurance of safety can be determined by cross referencing against published safety manuals (i.e. “Reference Manual for Magnetic Resonance Safety, Implants, and Devices. Frank G. Shellock), or by obtaining written documentation including the FDA date stamp verifying the device is MRI safe within the specific conditions used for the study.  Conditional safety must be carefully considered as some hazards depend on the specific MR machine and type and duration of scanning sequence.  In addition, the same individual who may be allowed to have a ***clinical*** MRI scan may not be allowed to have a ***research*** scan because the risk to benefit ratio calculation in the context of patient care does not apply to research.  In instances of insufficient documentation, decisions will be made on a case-by-case basis by the MRI Facility Staff.
3. REMOVE NON-MRI COMPATIBLE ITEMS: If the participant clears the screening form, they will then be asked to remove all non-MRI compatible items such as cell phones, keys, credit and metro cards, etc.  Changing rooms with lockers are available for their privacy.
4. METAL DETECTION, LEVEL 1: FERROUS AND NON-FERROUS: Once the participant has removed items not compatible with MRI, a trained individual will use a hand-held metallic sensing wand specifically designed for MRI screening.  At first pass, the metal detector screens for any items with metallic content.  If detected, a second pass is done with the metal detector's settings adjusted to screen for only ferrous metal (which is metal that will experience strong magnetic attraction from the MRI scanner).  This step is important for distinguishing between some MRI safe items of non-ferrous metallic content (i.e. belt buckle, zippers, clothing buttons, titanium implants, non-removable earrings) that the participant may safely be scanned with and other unsafe MRI items of ferrous metallic content (steel implants, iron filings/shrapnel).
5. METAL DETECTION, LEVEL 2: WHOLE BODY, HIGH SENSITIVITY, FERROUS-ONLY SENSORS: After the above steps have been completed and passed, the participant is cleared for MRI safety.  As a final, redundant, safety measure, the doorway into the MRI scanner suite is lined with an extremely sensitive, whole body, ferrous only detector.  24 sensors line the frame of the door.  The MRI operator, standing inside the scanner suite, will observe the participant and the sensor array as the participant passes through the door threshold.  If any of the 24 detectors senses ferrous metal, an alarm is sounded and red lights appear at the location of the sensors closest to what triggers the alarm.  The participant then stops before entering further and is inspected in the area where the sensor detected metal.  This process is repeated until all unsafe items are removed from the participant and he/she is deemed ready to be scanned.
6. The above steps take place in chronological order, prior to any scanning, each step taking less than a few minutes on average.