



February 21, 2023

Dear Colleagues:

Given the increasing use of magnetic resonance imaging (MR) in research, a new requirement for the review by a Protocol Review Subcommittee (PR Subcommittee) of the Joint MR Research Safety Committee of certain protocols involving the use of MR has been instituted as a component of the University's Institutional Review Board (IRB) protocol review process.

The Rascal IRB Application has been revised to assist you in determining if the new process is applicable to your study. If you indicate in the "Imaging Procedures" section of the Application that MR scanning will be used in the study, and imaging procedures are beyond those that would be used for clinical diagnostic or treatment purposes, you will be required to answer a short set of questions in Rascal. Based on your responses, you may have to complete a Hazardous Materials Appendix R (Appendix R) and attach it to the Application. The Appendix will be referred to the PR Subcommittee for its review. Once approved, the IRB will be notified and the IRB review may be finalized. This process is similar to the current procedure for approving studies that use ionizing radiation, which must be approved by the Human Use Subcommittee of the Joint Radiation Safety Committee prior to IRB approval.

Specifically, research studies involving any of the following factors will be required to be submitted to the PR Subcommittee for review:

- Operation of new or custom (i.e., non-FDA approved) imaging equipment (e.g., coils, receivers, etc.)
- Use of non-manufacturer-provided pulse sequences that exceed the scanner "Normal Mode" or, for scanning of healthy subjects, the scanner "1st Level Control Mode"
- Enrollment of healthy pregnant or minor subjects.

If needed, Appendix R will request the following information:

- Location of scanning and equipment to be used
- Use of non-FDA approved imaging in the scan, if applicable
- Use of non-manufacturer-provided pulse sequences that exceed the scanner "Normal Mode" or, for scanning of healthy subjects, the scanner "1st Level Control Mode", if applicable
- Names of MR Operator and other personnel performing scans
- Equipment or materials from outside the applicable MR facility to be used in the scanner room during scanning procedures
- Use of contrast, sedation, or other medication, if applicable
- Scan time per session and number of sessions per subject
- Justification for the use of healthy pregnant or minor subjects, if applicable.

If you need assistance answering the Rascal questions or completing the new Appendix, please contact Peter Caracappa at pc2837@cumc.columbia.edu or Brenda Ruotolo at blr2102@cumc.columbia.edu

Sincerely,

Peter Caracappa
Executive Director & Chief Radiation Safety Officer, Environmental Health and Safety

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