

RASCAL APPENDIX R: REVIEW PROCESS FOR PROTOCOLS INVOLVING MRI

Monthly IRB-Investigator Meeting
August 24, 2023

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MRI in Human Subjects Research

- Magnetic Resonance Imaging (MRI) is often considered a minimal risk procedure in research
 - Non-invasive
 - Does not involve ionizing radiation
- Still capable of causing injury or death if not performed properly
- Is of increased concern for sensitive populations



MRI Hazards

- Projectiles



MRI Hazards

- Projectiles
- Burns



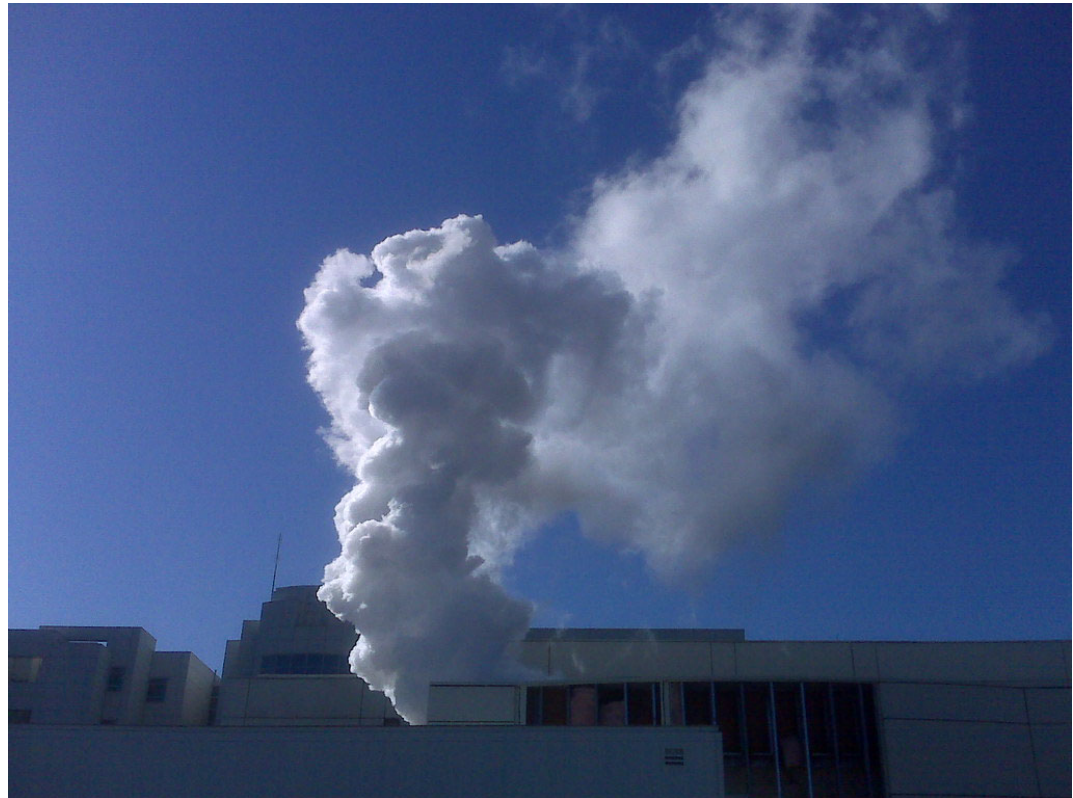
MRI Hazards

- Projectiles
- Burns
- Noise



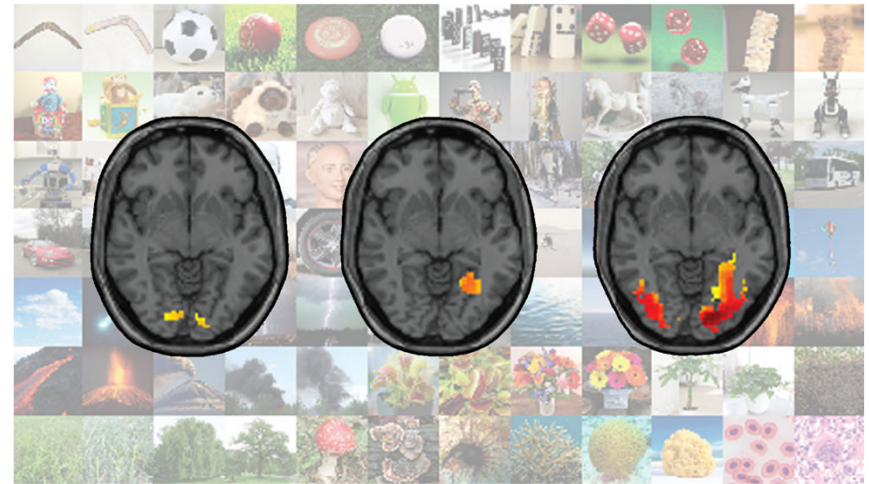
MRI Hazards

- Projectiles
- Burns
- Noise
- Quench



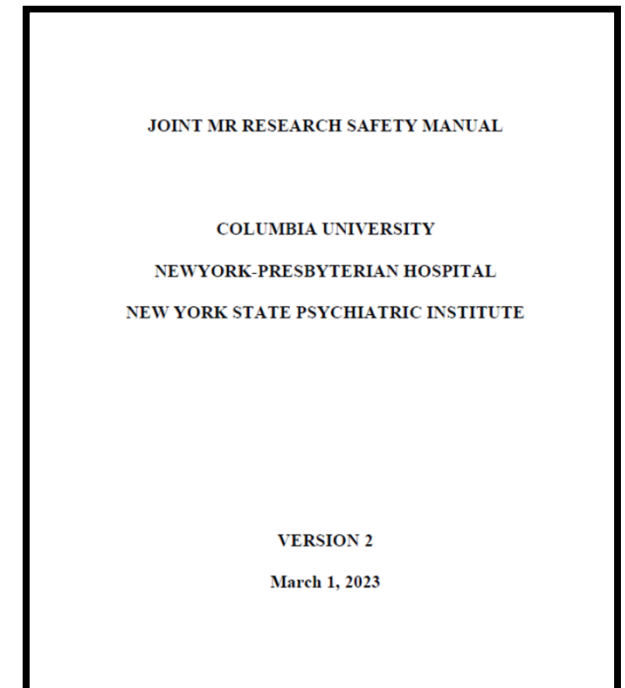
MRI Facilities at Columbia

- Zuckerman Institute SC4
- Neurological Institute basement
- NYSPI



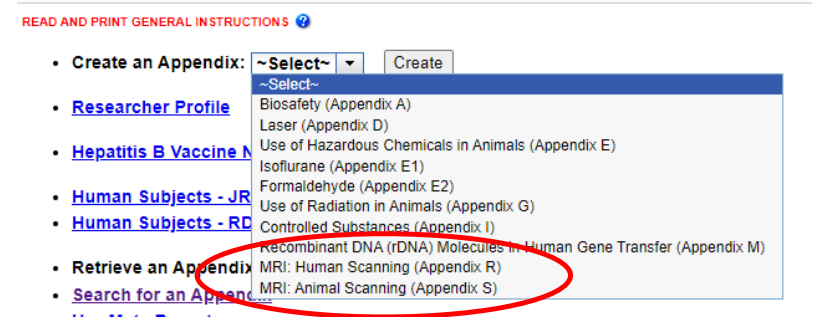
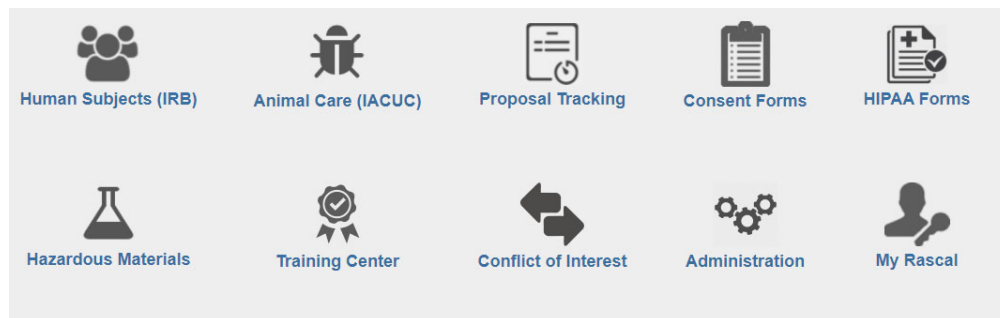
MR Research Safety Program

- Identified need for consistent policies in MR Safety across campuses, and to provide guidance to researchers that may want to use clinical MRI machines as part of their research. Does not include:
 - Clinical MRI procedures
 - Clinical research where MRI is a clinical tool
 - Small animal MRI devices
 - Laboratory NMR
- Established a Joint MR Research Safety Committee
 - Representation across campuses
 - General oversight of MR safety policies and procedures (does not replace local facility operational responsibility)
 - Review of safety issues and corrective actions



Rascal HazMat Appendices

- Human Studies (under certain criteria) – Appendix R



- Protocol Review Subcommittee for approval

Studies Requiring an Appendix R

- 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
- MRI procedures that are within the Standard of Care, or equivalent to Standard of Care for research purposes (outside of SOC frequency or indication) do not require an appendix

Appendix R – Information Requested

- Location of scanning
- Identify if non-FDA approved equipment is being used
- List of equipment or materials used during scanning (MRI compatibility)
- Who will be performing scans
- Use of contrast, sedation, other medication
- Estimated scan time per session and number of sessions per subject
- Inclusion of minor or pregnant subjects, with justification

- Review of consent/assent forms for subjects

Appendix Review Workflow

- Appendix R is attached to IRB protocol and protocol is submitted
 - IRB will not act on protocol until Appendix is approved
 - If IRB returns protocol (for another reason) the appendix will not be accessible to reviewers until protocol is resubmitted
- EH&S reviews appendix for completeness of information
 - Will be “held” if something additional is needed
- Appendix is distributed to MRI Protocol Review Subcommittee
- Based on committee vote, appendix will either be approved or held with additional comments

Questions?

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