

Monthly IRB-Investigator Meeting: MRSC and IRB Review

August 24, 2023

Brenda Ruotolo
AVP for Human Research Protection

Primary Presentation

Peter F. Caracappa, Ph.D., PE, CHP
Chief Radiation Safety Officer
Columbia University
NewYork-Presbyterian Hospital

Joint MR Research Safety Manual:

https://research.columbia.edu/sites/default/files/content/EHS/Rad%20Safety/JointMR_ResearchSafetyManual.pdf

Studies Requiring PR Subcommittee Review

Research studies involving any of the following factors are 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”; or
- Enrollment of healthy pregnant or minor subjects.

Questions in IRB Form

Imaging Procedures/Radiation Therapy

*Will a contrast agent (e.g., iodine containing, gadolinium containing, barium sulfate) be used in conjunction with imaging procedures that go beyond the parameters established for the applicable standard of care (SOC), or will a contrast agent be administered for research purposes only? (The appropriate response will be 'no' if use of contrast in imaging is solely in SOC procedures).
☐ Yes ☐ No

For each type of radiation exposure (e.g., ionizing: CT, X-ray; non-ionizing: MRI), identify the procedure and whether the administration (e.g., radiation dosage, number or type of scans) is clinically indicated and in accordance with the parameters established for the applicable standard of care (SOC), or is "beyond" these parameters (i.e., includes procedures or exposure for research purposes only).

Add Procedure(s) Involving Ionizing Radiation

Procedure(s) Involving Ionizing Radiation

Procedure

Add Procedure(s) Involving Non-Ionizing Radiation

Procedure(s) Involving Non-Ionizing Radiation

Procedure	
MRI	Beyond that established for the applicable SOC
MRI	Beyond that established for the applicable SOC

Save

Contact Us | @ Columbia University

Please contact the Human Research Protection Office if you have questions about submitting to the IRB, or whether this study requires review.

***Procedure:**
☐ fMRI ☒ MRI ☐ Ultrasound ☐ Other

***Location:** Hatch (based in neurological institute)

***Are the scanning procedures being administered considered to be:**
☐ As established for the applicable SOC
☒ Beyond that established for the applicable SOC
☐ Both within and beyond that established for the applicable SOC

***1. Will healthy pregnant subjects be enrolled and undergo MR scanning procedures?** ☐ Yes ☐ No
***2. Will healthy minor subjects be enrolled and undergo MR scanning procedures?** ☐ Yes ☐ No
***3. Will new or custom (i.e., non-FDA approved) imaging equipment be used?** ☐ Yes ☐ No
***4. Will non-manufacturer provided pulse sequences be used that exceed the 'Normal Mode' or, for scanning of healthy subjects, the scanner '1st Level Control Mode'?**
☐ Yes ☐ No

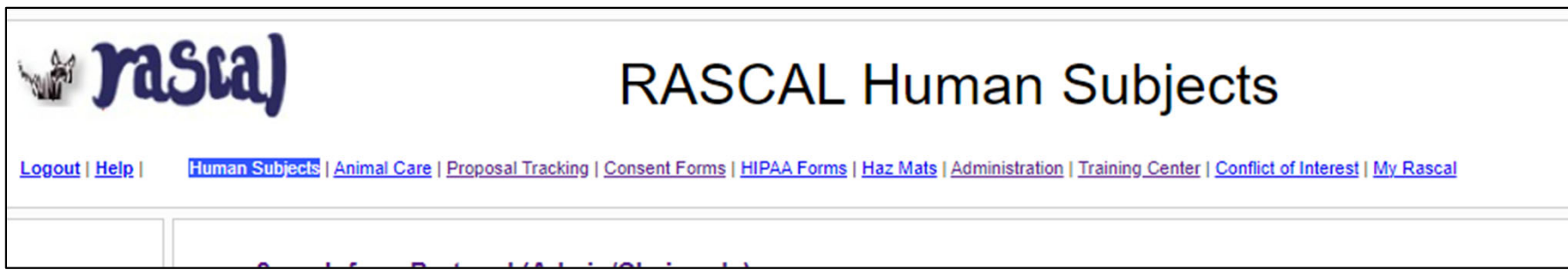
Note: An Appendix R will be required if the response to any of the above questions (1-4) is 'Yes'.

If you are enrolling any healthy volunteers, you cannot select only 'As established for the applicable SOC'.

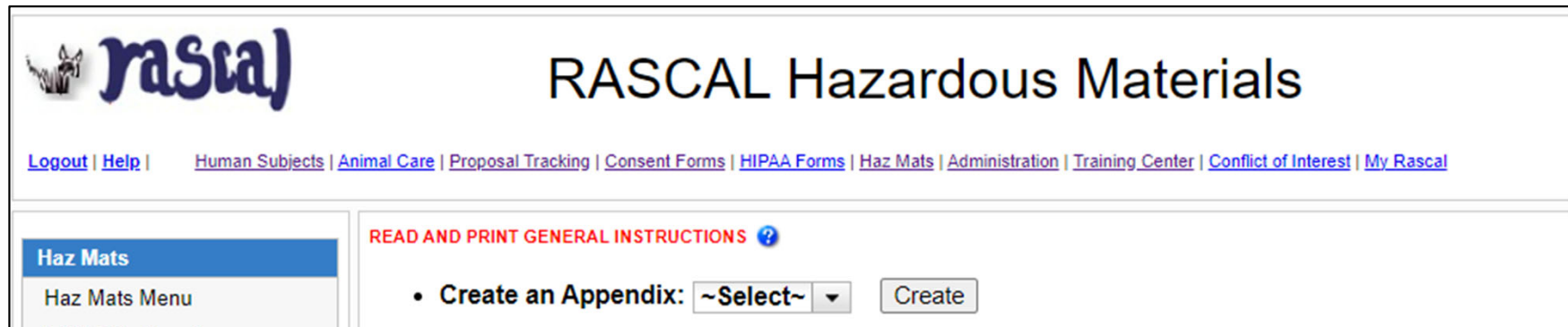
Save

Appendix R

- Select “HazMats” in Rascal



- Create an Appendix



HRPO/IRB View

On the View (Protocol, Modification, etc) History page:

Hazardous Materials History			
Hazard	Appendix	Status	Approval History
MRI: Human Scanning (Appendix R)	APR-AAAA5052	Approved	Safety Office - Approved - Peter Caracappa - Apr 06 2023 4:51 PM Safety Office - Held by Approver - Peter Caracappa - Mar 30 2023 5:37 PM Safety Office - no action
Human blood, all human cell lines or other potentially infectious materials (OPIM)	Not required	Completed	PI Attested on 03/24/2023
1 - 2 of 2 results			

On the Datasheet:

Procedure(s) Involving Non-Ionizing Radiation		
Procedure	The exposure to:	Location:
MRI	Both within and beyond that established for the applicable SOC	Other
	1. Will healthy pregnant subjects be enrolled? Yes	
	2. Will healthy minor subjects be enrolled? No	
	3. Will new or custom (i.e., non-FDA approved) imaging equipment be used? No	
	4. Will non-manufacturer provided pulse sequences be used that exceed the 'Normal Mode' or, for scanning of healthy subjects, the scanner '1st Level Control Mode'? No	

Be sure information is consistent between Appendix and Datasheet.

Consent Language

- <https://research.columbia.edu/irb-protocol-and-consent-form-resources>
- [Model MR risk language](#)
- <https://research.columbia.edu/human-research-policy-guide>