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

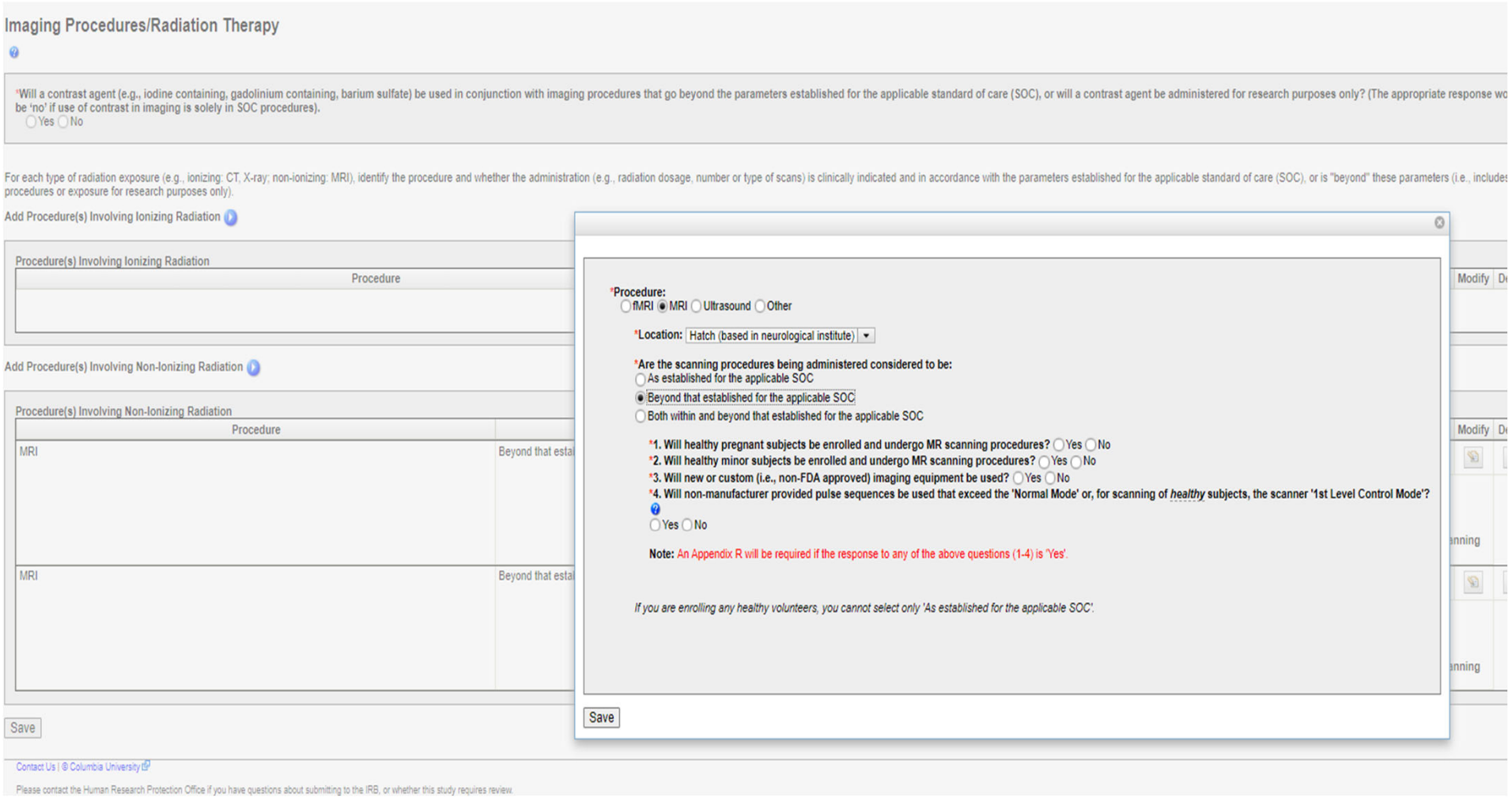
Joint MR Research Safety Manual:
https://research.columbia.edu/sites/default/files/content/EHS/Rad%20Safety/JointMR_ResearchSafetyManual.pdf

Studies Requiring PR Subcommittee Review

Research studies involving any of the following factors are required to be submitted to the PR Subcommittee for review:

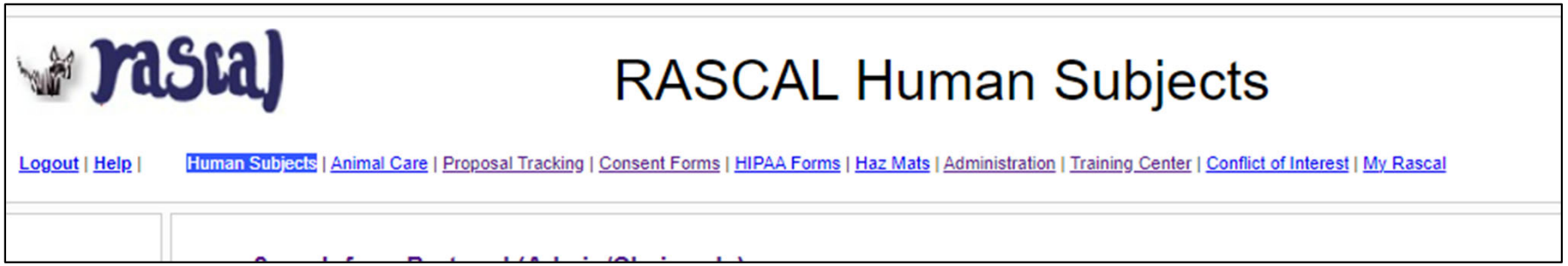
- Operation of new or custom (i.e., non-FDA approved) imaging equipment (e.g., coils, receivers, etc.);
- Use of non-manufacturer-provided pulse sequences that exceed the scanner "Normal Mode" or, for scanning of healthy subjects, the scanner "1st Level Control Mode"; or
- Enrollment of healthy pregnant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

Questions in IRB Form

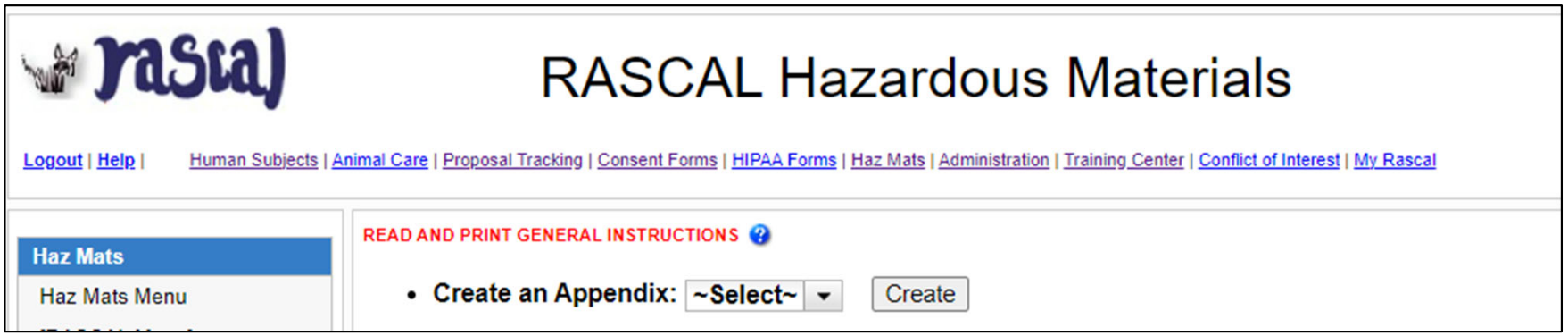


Appendix R

- 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