CAMRIS SOP #307

Evaluation and Approval of Devices Designed to Emit or Modulate Radiofrequency Fields

Responsible Committee:	Effective From:	Last Approved:	Next Review:	Next Approval:
Safety	September 1, 2025	Aug 27, 2025	March 30, 2026	April 30, 2026

1. Purpose

This standard operating procedure (SOP) describes the process used by CAMRIS to reduce the risk of devices that emit or modulate radiofrequency fields and thus have thermal safety implications for human subjects research.

2. Scope

These procedures apply to all RF-emitting or -modulating devices used in human subjects research within research MRI facilities; this includes both CAMRIS-managed facilities and clinical-shared facilities during times they are under operation by CAMRIS.

3. Instructions and Procedures

3.1. Regulatory documentation of human subjects safety

3.1.1. FDA-approved devices

Documentation of FDA approval, including the conditions under which safety has been approved, will be accepted as sufficient documentation of device safety for human subjects research.

3.1.2. CE-approved devices

Documentation of CE approval, including the conditions under which safety has been approved, will be accepted as sufficient documentation of device safety for human subjects research.

3.2. Third-party expert evaluation of human subjects safety

To support the use of experimental RF-emitting and -modifying devices that do not have formal approval from a regulatory body, third-party expert evaluation is required by CAMRIS to support approval for human subjects research. Depending on the device in question, CAMRIS will work with study teams to identify an appropriate expert from outside the Penn community who can act as a third-party evaluator without conflict of interest.

3.2.1. Elements of third-party expert evaluation

A third-party expert in the evaluation of RF safety for MRI must document that safety testing has been performed consistent with community standards, as outlined in the publication "ISMRM Best Practices for Safety Testing of Experimental RF Hardware".

3.2.2. Authorization of third-party expert evaluation

To ensure appropriate expertise and minimize potential and perceived conflicts of interest, third-party evaluators must be approved by CAMRIS. At minimum, CAMRIS-approved experts should meet the following standards:

- The expert should have documented expertise in the evaluation of RF coils in the context of MRI. This can include academic publications and/or professional experience.
- The expert cannot have a separate commercial relationship with UPenn or HUP relevant to the equipment being evaluated. Employees of companies that currently purchase or sell equipment or services to UPenn or HUP relevant to the equipment being evaluated, or where such a purchase or sale can be reasonably anticipated, cannot serve as expert evaluators.
- The expert cannot have academic collaborations with UPenn relevant to the equipment being evaluated within the last 5 years. Joint academic publications or patents will be considered evidence of collaboration, but CAMRIS may consider other evidence of academic collaboration as well.

3.2.3. Payment for third-party evaluation

Research groups that are purchasing a new coil are expected to pay all costs associated with documenting safety for human subjects. CAMRIS may support a portion of the cost of the external consultant, particularly when the proposed experimental device will be used by multiple research groups.

3.3. Documentation of compatibility with Siemens MRI Scanners

Human subjects safety approval as described in section 3.1 and 3.2 does not evaluate the compatibility of a coil with Siemens MRI scanners; this must be separately documented.

3.3.1. RF coils purchased directly from Siemens

Coils purchased from Siemens, regardless of manufacturer, are tested by Siemens to ensure compatibility and CAMRIS does not require further compatibility documentation for these coils.

3.3.2. RF coils purchased from a third-party manufacturer

Coils that are purchased from a third-party manufacturer must document compatibility with Siemens' RF coil design specifications. Manufacturers who are part of the Siemens RF coils collaborations program ("Siemens MLCP") will have access to appropriate documentation and must provide written attestation that they have followed the guidelines laid out in their MLCP agreement. Vendors who are not part of the MLCP program must provide detailed documentation demonstrating their design and manufacturing complies with Siemens' specifications. If vendors cannot provide sufficient documentation, CAMRIS can work with researchers to help identify a suitable expert who can document the coil's design, but this may require disassembling the coil with attendant impacts on warranties and regulatory certifications.

3.3.3. RF coils manufactured locally

Locally manufactured coils must follow the guidelines laid out in Penn's collaborations

agreement with Siemens, including all elements of the Siemens MLCP agreement. CAMRIS can provide access to this documentation on request.

3.4. Submitting documents for device approval

Device approval may be requested through the CAMRIS Service Desk.

4. Update History

Date:	Description of Revision
May 7, 2025	Initial version
Aug 27, 2025	Expanded section 3.2 to provide guidelines for selection of third-party expert reviewers Added section 3.3 Renumbered previous section 3.3 to 3.4