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	May 28, 2025	May 28, 2025	April 1, 2026	May 28, 2026

1. Purpose

This standard operating procedure (SOP) describes the process used by CAMRIS to ensure the safety 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 accepted by CAMRIS

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 (European Union regulatory) 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 accepted by CAMRIS

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 may be considered by CAMRIS to support approval for human subjects research. A third-party expert in the evaluation of RF safety for MRI must document that safety testing has been performed consistent with community standards, in particular as outlined in the publication “ISMRM Best Practices for Safety Testing of Experimental RF Hardware”. Devices must also comply with all recommendations from Siemens Healthineers for the safe design of RF coils (documentation of these standards can be provided by CAMRIS).

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.

3.3. 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