

CAMRI High-Risk Procedures Policy

The primary objective of this policy is to protect the health and safety of our patients and users as well as to the operational integrity of CAMRI. Our highest priority is to minimize potential hazards and ensure the highest safety standard within our center. To this end, CAMRI must prevent from be conducted, and prohibit CAMRI staff from operating equipment for, any procedures deemed high risk by the Core.

High-risk procedures include, but are not limited to, those involving:

- Non-approved implantable devices.
- Procedures or protocols not validated by standard clinical guidelines.
- Procedures on patients with high risk MRI contraindications.
- Procedures or experiments requiring an exemption from other policies.

Procedure Risk Assessment:

- All proposed MRI procedures must undergo a risk assessment review by CAMRI before study initiation.
- All patients must undergo a safety evaluation based on the patient's medical history, the nature of the procedure, and other relevant factors as determined by CAMRI.

Decision Making:

- After protocol review, the PI will be notified if the procedure is classified as anything other than standard risk, whether the protocol can be run at CAMRI, and if applicable any additional safety, staffing, or other requirements that must be satisfied to run the study at CAMRI.
- For patients who are deemed to be anything other than low risk by the study team, clearance must be obtained from their Level 2 trained user. For any patient that the Level 2 trained user cannot classify as anything other than low risk, the study team must obtain clearance from CAMRI's Senior Technologist, Lacey Delay, PRIOR to scheduling the procedures on CAMRI equipment. The study team will be notified whether the patient can undergo the proposed procedures at CAMRI, and if applicable any additional safety, staffing, or other requirements that must be satisfied to work with the patient at CAMRI.

Training:

- All CAMRI Staff, PI's, and Level 1 & Level 2 trained Users are required to receive periodic training on identifying high-risk factors, responsibilities of the study team, and correct protocols to prevent unauthorized procedures.

Compliance:

- Strict adherence to this policy is mandatory. Violations of this policy may result in disciplinary action, such as termination of scanning privileges at CAMRI.