CAMRIS SOP #302

Scanning Research Participants with Cardiac Implantable Electronic Devices (CIEDs) at Stellar Chance

Responsible Committee:	Effective From:	Last Approved:	Next Review:	Next Approval:
Safety	July 12, 2024	July 12, 2024	June 1, 2025	July 1, 2025

1. Purpose

This standard operating procedure (SOP) defines the policies for research MRI studies in research participants with Cardiac Implantable Electronic Devices (CIEDs) at the Stellar Chance MRI facility.

2. Scope

Although MRI in participants with CIEDs is associated with additional risks and requires additional precautions, it can be performed safely. This SOP addresses the requirements for performing MRI studies in research participants with CIEDs at the Stellar Chance MRI facility, which is not located in a clinical area and not accessible by Penn Medicine clinical support teams. These policies do not override any policies created by the relevant clinical services or health system.

3. Instructions and Procedures

3.1. Overall responsibility for the participant safety

CAMRIS does not itself offer any services for CIED management during research MRI. The Principal Investigator of any research MRI protocol in participants with CIEDs is responsible for providing the personnel and expertise to carry out the research and takes full responsibility for participant safety while using CAMRIS MRI facilities.

3.2. Ethical Consent

All participants with CIEDs undergoing research MRI must provide informed consent within an IRB-approved protocol that explicitly addresses CIED use outside of health system facilities.

3.3. Equipment, Personnel, and Procedures

Research MRI in participants with CIEDs follows published guidelines developed for clinical MRI on behalf of and approved by the International Society for Magnetic Resonance in Medicine Safety Committee (https://onlinelibrary.wiley.com/doi/10.1002/jmri.27320), the key elements of which are outlined below.

3.3.1. CIED compatibility

Only participants with CIEDs designed to be MRI conditional are eligible for research MRI studies at SCL MRI. It is up to the investigative team to verify via the vendor's official product

documentation that the implant is compatible with the specific MRI system and pulse sequences used in the research MRI protocol, including SAR, gradient slew rates, and static field strengths. CAMRIS staff can consult on making this determination for individual cases, but it remains the responsibility of the PI.

3.3.2. Required ancillary equipment for MRI studies in participants with CIEDs at SCL MRI
All studies in participants with CIEDs must be carried out with continuous heart rate monitoring using an MRI compatible pulse oximeter supplied by the investigative team. In addition, the investigative team is responsible for providing the instrumentation and expertise required to interrogate the CIED and switch into and out of MRI safe mode.

3.3.3. Required staffing for MRI studies in participants with CIEDs at SCL MRI
All studies in participants with CIEDs must by supervised by a medical provider (MD or NP) with expertise in cardiac monitoring and active ACLS certification. This individual must have Level 1 (MRI safety) training and be physically present in the MRI suite throughout the duration of the study and is additionally responsible for ensuring the proper implementation and use of the MRI compatible pulse oximeter and for monitoring heart rate throughout the MRI study. This individual cannot be the MRI operator. In the unlikely event of a medical emergency, the MRI operator will be responsible for activating emergency medical support.

3.3.4. The study team is responsible for maintaining documentation of the CIED study. This documentation must include 1) the IRB protocol number for the study, 2) a description of the CIED device, 3) an assertion that the device was determined to be compatible with the research MRI protocol, 4) the date of the study, 5) the time the CIED was decommissioned, 6) an assertion that the MRI scanner was operated in the appropriate mode, 7) the time that the CIED was recommissioned, 8) An assertion that either the study was completed without complications or a summary of any adverse complications. The documentation must be signed by 1) the study PI or their designate responsible for medical oversite, 2) the person responsible for decommissioning and recommissioning the CIED, and 3) the MRI operator.

3.3.5. Failure to comply with any of these policies and procedures will result in suspension of the CAMRIS protocol.

4. Update History

Date:	Description of Revision
July 12, 2024	Initial version