ANCILLARY EQUIPMENT POLICY

ALL ancillary equipment must be approved by CBI's MRI Technologists prior to being brought into the 3T or 7T scanner room. At their discretion, technologists may approve devices or send them for full review to CBI's MR Safety Committee. ALL objects containing metal pose potential risks including tissue burns and projectile trauma. Manufacturer guidelines are not necessarily sufficient to ensure safety for the CBI's specific MRI systems.

Requests to approve new equipment, devices, or implants as MR Conditional or MR Safe should be emailed to CBItech@musc.edu or communicated by phone at 2-2353.

It is strongly recommended that requests be made several months prior to intended use. If the technologist decides to submit the device to the full MR Safety Committee, the approval process may require an in-depth analysis of the interaction of the object with the electromagnetic field generated by the scanner. In some cases, approval may be conditional on specific procedures being followed.

IF an in-depth analysis by the MR Safety Committee is required, investigators must supply the information indicated on the checklist below.

MR Safety Committee's Ancillary Equipment Approval Request Checklist

- ❑ Provide all relevant documentation on device from manufacturer (including manuals, MR safety tests, manufacturer MRI-related information, technical publications reporting investigational use, certifications by third parties, …).
- ❑ Provide details on intended use of device with MRI, including research protocol.
- ❑ Describe research team's expertise and past experience in using similar ancillary devices with MRI.

Once all documents are received, CBI's MR Safety Committee will evaluate based on the following criteria:

- Is the device listed in *The Reference Manual for Magnetic Resonance Safety, Implants, and Devices*?
- Does the device meet ACR guidelines?
    - This includes following ASTM standards to minimize projectile injury, burns, induced electrical currents and interference risks, as well as appropriate labeling for all components and MR Conditional status.
- Does the device pose significant risk to the subject? Will a registered nurse, patient monitoring equipment, radiologist, emergency medical staff, crash cart, medications, etc. be on site to ensure subject safety?
    - Note CBI has no such staff or equipment and does not have immediate access to the emergency resources of the MUSC hospital system—only 911.
- Does the research group have sufficient expertise and experience to utilize the device safely, given the level of risk involved to subjects?

Evaluation will be based on established MR safety standards, professional experience of CBI staff, and a comprehensive risk analysis. Safety will be prioritized with the goal of negligible risk of subject harm.

Ancillary equipment submitted to the MR Safety Committee can only be approved by unanimous vote of all members of the Committee.

For additional information on the requirements for devices entering the MR environment, please refer to the ACR Manual on MR Safety and the FDA's guidelines on Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment