CAMRIS SOP #306

Screening for Pregnancy and Scanning Pregnant Participants

Responsible Committee:	Effective From:	Last Approved:	Next Review:	Next Approval:
Safety	Oct 1, 2024	Oct 1, 2024	Sep 1, 2025	Oct 1, 2025

1. Purpose

This standard operating procedure (SOP) describes the guidelines required by CAMRIS for studies where this is a possibility that participants may be pregnant. Pregnant participants are often under-represented in research, and so CAMRIS's policies are designed to ensure that they can be appropriately included research studies where the risk is minimal. These policies are designed to broadly align with the recommendations of the American College of Radiology (https://www.acr.org/-/media/ACR/Files/Radiology-Safety/MR-Safety/Manual-on-MR-S afety.pdf), but are specific to the environments managed by CAMRIS.

2. Scope

These procedures apply to all studies scanning participants in 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. Screening for pregnancy

Consistent with the minimal risk of MRI during pregnancy CAMRIS does not generally require that subjects who can become pregnant be tested prior to participating in MRI studies. Unless otherwise specified, CAMRIS instead requires only participant attestation that they are not pregnant within 12 hours prior to each MRI scan.

In specific cases, based on the participant population being recruited (*e.g.*, participants who are currently trying to become pregnant), CAMRIS may require a negative urine pregnancy test within 12 hours prior to the MRI scan. Studies for whom this test is required will be notified at the time of protocol approval.

For studies that do not wish to test for pregnancy, an alternative is to ensure the protocol matches the limitations enumerated in section 3.2 and include the relevant ICF clause describing the risks of MRI in pregnancy.

3.2. Limitations on imaging protocols for pregnant participants

MRI during pregnancy is broadly considered safe for clinical and research use. To ensure that there is minimal risk to the pregnant participant and the fetus, CAMRIS imposes the following limitations on scanning protocols, consistent with ACR guidelines:

3.2.1. Research topics
Studies that wish to enroll pregnant participants must demonstrate that the outcome measures are likely to depend on pregnancy. Where pregnancy is not likely to affect outcomes, pregnant participants should be excluded.

3.2.2. Gadolinium-based contrast
Gadolinium-based contrast cannot be used for research studies in any subject who is pregnant.

3.2.3. SAR limits at 3 T and lower field strengths
All studies at 3 T and lower field strengths must be run in Normal Mode (i.e., <= 2 W/kg) with the body transmit coil in circularly polarized mode.

3.2.4. Peripheral nerve stimulation limits
All studies must be run in Normal Mode for peripheral nerve stimulation. Studies cannot proceed if the scanner warns that the subject will experience peripheral nerve stimulation.

3.2.5. Use of local transmit coils
The use of local transmit coils must be specifically approved by CAMRIS before they are used in pregnant subjects. General approval of a local transmit coil for use in human participants must not be interpreted as approval for pregnant participants unless explicitly stated in your approval letter.

3.2.6. 7 T
Pregnant participants cannot be scanned at 7 T for research studies.

4. Update History

Date:	Description of Revision
Sept 11, 2024	Initial version