1. Introduction

The purpose of this SOP is to outline the comprehensive steps and guidelines necessary for obtaining CIRC PRC approval and conducting human research studies. Adhering to these procedures ensures that all research activities are conducted ethically, legally, and in accordance with institutional and regulatory requirements.

2. Scope

This SOP applies to all study personnel (PI, research coordinator, …), wishing to use the MRI scanner at CIRC.

3. Definitions

**Institutional Review Board** – A committee that reviews and approves research involving human subjects to ensure ethical standards are met.

**CIRC Protocol Review Committee (PRC)** – An internal committee consisting of at least four reviewing members. Membership may include the CIRC manager, the MRI technologist, and CIRC-affiliated faculty. PRC meetings are held on the last Tuesday of every month to review research protocols involving the CIRC.

**Study Team** – Faculty, staff and students conducting a research project.

4. Policies and Procedures

The CIRC is available to researchers conducting human subject research. To conduct a research study in the CIRC, the following instructions must be followed:

**4.1. CIRC’s Approval Process**

4.1.1. *Submit your research protocol (same document intended for IRB review) to the CIRC PCR for review.*

4.1.2. The PRC Chair will assign a primary and secondary reviewer.

4.1.3. The PRC will review the protocol at its monthly meeting. The primary review criteria being assessed are study safety and feasibility.

4.1.4. Possible PRC outcomes include: 1) Approve, 2) Approve with stipulations, or 3) Defer.

- If approved, the PI will receive an approval letter from the CIRC that should be included with your IRB application.
4.1.5. Upon final IRB approval, the CIRC manager will schedule an implementation meeting with the PI.

*NOTE:* You may initiate the IRB and CIRC approval processes in parallel. However, please be advised that IRB approval depends on CIRC approval.

4.2. Post-CIRC & IRB Approval

4.2.1. The CIRC manager will schedule an implementation meeting with the PI.
- Review project services and staff needs.
- Review Study Team Expectations.
  - Research Coordination.
  - Scan preparations (scrubs, MRI screening form, etc).
  - Assist in emergency removal from scanner if needed.
  - CPR certification if needed.
- Schedule in-person safety training with study team members.
- Center tour.
- Set up iLab account/schedule on iLab.
- MRI Safety Screening Form.
- Review service agreement.

4.2.2. Upon finishing the safety training and submitting screening form, badge access will be granted to study team members.

4.2.3. Ensure your access is activated before the first scheduled visit.

4.3. Study Modifications

4.3.1. *Submit research protocol modifications to the PRC.

4.3.2. Minor modifications (not changing scope of MRI or safety of the MRI portion of project) will be reviewed and approved by the PRC chair.

4.3.3. Modifications impacting scope and/or safety of the MRI will be reviewed by the full PRC.

4.3.4. Upon PRC approval, submit research protocol modifications to the IRB for review.

*NOTE:* You may initiate the IRB and CIRC approval processes in parallel. However, please be advised that IRB approval depends on CIRC approval.

4.4. Protocol Development/Calibration Subjects

Researchers are encouraged to develop their protocol prior to the first scheduled study visit with a human participant. This will help ensure feasibility and maximize data quality.
4.4.1. Test subject(s) for this purpose are the responsibility of the study team (i.e. recruitment, consent, etc.).
   o For minimal risk standard imaging protocols, the CIRC umbrella IRB protocol may be used for this purpose. Please check with the CIRC manager well in advance to ensure compatibility and availability.
   o For more involved protocols, the study team will need to use their own IRB approved protocol that allows for protocol development/calibration subjects.
   o Regardless of which option is used, the study team is responsible for all associated costs.

4.4.2. It is recommended to schedule the scanner for a minimum of **3 hours** (may be non-consecutive, depending on protocol and study design) to have enough time and assess how much time you need for the actual study, and to establish the imaging protocol and procedures.

4.4.3. Report any changes to the CIRC Review Committee and the IRB (through a protocol modification).

5. Document History

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<th>Description of Change</th>
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<td>06/26/2024</td>
<td>Original Version</td>
<td>Aida Nasirian &amp; Mike Nelson</td>
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