MINIMAL RISK USAGE OF THE CALTECH BRAIN IMAGING CENTER (CBIC-human)	SOP 4.2.04

1. Purpose & Policy

The purpose of this SOP is to provide guidelines for determining risk for magnetic resonance imaging (MRI) studies performed in the human imaging facilities of the Caltech Brain Imaging Center (CBIC-human).

2. General Information

The Caltech Brain Imaging Center (CBIC) is a collective of imaging facilities defined by a charter adopted in May 2024 (Appendix A). Investigators use the CBIC's state-of-the-art facilities to conduct research studies of the brain in both humans and animals. The following SOP applies to the human neuroimaging sub-facility of the CBIC (CBIC-human)

Neuroimaging research projects in human participants are conducted using a Siemens 3.0 Tesla PrismaFit MRI scanner, in a dedicated human participant fMRI laboratory. The system provides a variety of commercial head coils (CP transmit-receive, 20 channel, 32 channel and 64-channel receiver arrays), multipurpose flexible coil arrays and a two-channel parallel transmit body coil. The CBIC-human has a decades-long history of successful research for imaging the human brain. In the past, all human MRI protocols have been deemed "greater than minimal risk". However, there is good precedent at many other research institutions and substantive rationale for changing this default designation to "minimal risk," provided that certain criteria are met. This SOP formalizes those criteria.

3. Training Requirements

Other than the normally required and study specific training for all human subjects research, there are no specific training requirements associated with the procedures for recommending risk associated with MRI studies performed in the CBIC-human; however, investigators should carefully read and follow this SOP when submitting their IRB protocols involving MRI imaging in the CBIC-human facility.

4. Procedure

The CBIC-human has long-standing established safety procedures in place for ensuring a minimization of risk. This includes mandatory use of the CBIC-human MRI safety screening questionnaire and in person pre-screening for MRI-compatibility, as well as conducting MRI studies using the MRI in Normal Operating Mode. Use of Normal Operating Mode enforces FDA limits on

radiofrequency heating and peripheral nerve stimulation in both software and hardware, further reducing risk to the participant. Because these safeguards are in place, the IRB feels that, provided certain conditions are met, use of the CBIC-human MRI can be considered "minimal risk".

A. The IRB will consider an MRI study minimal risk if:

    1. The MRI system is in Normal Operating Mode, even with use of non-FDA approved pulse sequences; and
    2. The participant is a healthy, adult individual who passes the CBIC-human MRI safety screening questionnaire and in-person pre-screening; and
    3. The peripherals used in the scanner are limited to the pre-approved list, below:
        i. Eyelink 1000+ MR-compatible eyetracker
        ii. Current Designs product button boxes, trackball and joystick
        iii. NAtA Technologies product joystick and mouse
        iv. Sensimetrics S14 earbuds
        v. Biopac dermal electrode system with carbon fiber leads. Physiological and skin conductance monitoring only. EXCLUDES ELECTRICAL STIMULATION (Greater Than Minimal Risk)
        vi. Siemens Medical Solutions wireless physiological monitoring system for respiratory, ECG and peripheral pulse recording.
    4. The experimental tasks or stimuli are, themselves, no greater than minimal risk (e.g. audiovisual presentations, juice rewards, gain or loss of money in tasks); and
    5. The duration of any continuous MRI session is equal to or less than 2 hours; and
    6. Participants are not drawn from populations with a known clinical diagnosis that might put the participant at risk in the MRI (e.g., claustrophobia); Investigators should justify how any such clinical diagnosis inclusion criterion does **not** put the participant in additional risk being in the MRI; and
    7. No pharmaceuticals are administered as part of the study, including but not limited to, prescription and over-the-counter medications and MR contrast agents.

B. For protocols that do not meet all these criteria, or that include additional components not mentioned here, the IRB will consider all factors and will determine the risk category of the protocol on an individual basis.