

<b>MINIMAL RISK USAGE OF THE CALTECH BRAIN IMAGING CENTER (CBIC)</b>	<b>SOP 4.2.04</b>
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## 1. Purpose

The purpose of this SOP is to provide guidelines for determining risk for magnetic resonance imaging (MRI) studies performed in the CBIC.

## 2. General Information

Investigators at Caltech use the CBIC's state-of-the-art MRI scanners to conduct research studies of the brain and its mechanisms in human participants as well as animals. The CBIC facility houses three High-Field MRI systems and a variety of project support facilities. Cognitive brain mapping research projects are conducted using a Siemens 3.0 Tesla PRISMA MRI scanner, in a dedicated human participant fMRI laboratory. The system provides a variety of head coils (CP transmit-receive, 20 channel and 32 channel receive arrays and a 64-channel head-neck array), multipurpose flexible coil arrays and a two-channel parallel transmit body coil. The CBIC has a decades-long history of successful research for imaging the human brain. In the past, all such protocols have been deemed "greater than minimal risk". However, there is good precedent at many other 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

There are no specific training requirements for investigators associated with these procedures for recommending risk associated with MRI studies performed in the CBIC; however, investigators should carefully read and follow this SOP when submitting their IRB protocols for MRI imaging.

## 4. Procedure

The CBIC has long-standing established safety procedures in place for ensuring a minimization of risk. This includes pre-screening participants using CBIC's MRI safety screening questionnaire and in person screening, as well 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. Because these safeguards are in place, the IRB feels that, provided certain conditions are met, use of the CBIC 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's 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; and:

Preapproved list of peripheral devices used in CBIC MRI:

- 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 respiration, ECG and peripheral pulse
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<sup>1</sup> that might put the participant at risk in the MRI (e.g., claustrophobia); 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.

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<sup>1</sup> Investigators should justify how the clinical diagnosis does not put the participant in additional risk being in the MRI.