

Policies Concerning Human Subject Research

The Dynamic Imaging Science Center (DISC), herein referred to as the Center, is a research facility located in the Michelson Center for Convergent Biosciences, room LL 130, at the University of Southern California's University Park Campus. The Center is part of the Viterbi School of Engineering and is not affiliated with the Keck School of Medicine or Children's Hospital Los Angeles.

Magnetic Resonance Imaging (MRI) is the primary imaging technology used at the Center. As with other imaging performed at the Center, MRI scans are undertaken *for research purposes only*. Medically indicated diagnostic scans are not performed at the Center. The Center does not have medical or radiological staff to interpret MRI scans, thus no information regarding normal or abnormal findings will be provided to research participants by Center staff.

The Center, as a non-medical facility, together with the USC Office for the Protection of Research Subjects (OPRS) has established the following policy for MRI scans obtained for research purposes:

1. All subjects must be made aware that MRI staff *does not* have the requisite expertise to identify, interpret or communicate pathologic findings for diagnosis or treatment.
2. As there is no national requirement to have every research scan read by an outside radiologist, the Center will not be providing this service. Individual study principal investigators (PIs) should consult the IRB to determine whether they will be required to provide their own radiological review and reporting of incidental findings as part of their IRB protocol.

SUBJECT IDENTIFICATION

Subjects to be scanned at the Center are given a code number followed by the initials of the investigator. This is the "name" to be entered in the MR computer file, along with the subject's height, weight, sex and year of birth, as parameters required for setting up an MRI protocol. No actual name or any other identifying information is to be entered in the MRI console to make certain that subject privacy can be maintained. Individual investigators are responsible for keeping records in order to identify the raw data collected at the Center pertaining to their studies.

SUBJECT PROCEDURES

Investigators are responsible for obtaining IRB approval for their study and for filing the approval document with the Center. Investigators are also responsible for explaining informed consent procedures to every subject and having every subject sign the informed consent form. No subject may be scanned without a valid, signed informed consent form. The signed consent form must be presented to a designated Center staff member and a duplicate must be left at

the Center for secure filing. The code number assigned to the study will be added to the form. MR safety screening will be performed by the Center staff and will be signed by the subject and by the staff member performing the screening (see MR Safety Screening). Note that the screening results may preclude a subject from participating in a study. A copy of the signed screening form will be filed together with the informed consent form.

For subjects with a history of surgical procedures, or accidents, in connection with which metallic objects or particles might be lodged inside soft tissue, it is necessary to submit a medical report, signed by a physician, stating that it is safe for the subject to undergo MRI. This report needs to be filed together with the signed IRB and safety screening form.

Investigators are responsible for having one certified person accompany them to assist in the performance of the study.

IRB APPROVAL

All investigators who plan to conduct human subjects research at the Center must obtain IRB approval for their research protocols. Under no circumstances will an investigator be allowed to use the facility without submitting proof of IRB approval. Please use the UPIRB Informed Consent template for Non-Medical Research.

The Potential Risks and Discomforts section of this informed consent template includes mandatory language for DISC studies.

A copy of the Center mandatory language is provided below:

“The USC Dynamic Imaging Science Center (DISC) is a research unit, not a clinical or diagnostic Magnetic Resonance Imaging (MRI) center. The MRI scans obtained at DISC, such as the scan you are about to undergo, are research scans. They are not meant to provide medical diagnostic information. Many types of abnormalities will not be detected by this imaging, and you should not rely on this scan to find out if you are healthy or sick, or as a substitute for your usual medical care. If you are having symptoms, see your doctor.

However, on occasion, abnormalities may be seen on these research scans purely by chance. These rare occurrences are called incidental findings. Because DISC is not a clinical/diagnostic center, the center does not have radiologist staff members (medical doctors who can comment on MRI scans), and therefore we cannot tell if your scans show or do not show any abnormality.”

INCIDENTAL FINDINGS

Under no circumstances may an investigator, research staff, or the imaging center personnel interpret scans as normal or abnormal. All scans performed at the Center are for research purposes only and are NOT intended for clinical diagnoses or therapeutic purposes.

MRI SUBJECT AGREEMENT

All subjects must sign both Subject Agreement and study-specific informed consent documents.