



FIU IRB SOP for MRI Research at the Center for Imaging Science

SCOPE

Procedures for the handling of Magnetic Resonance Imaging (MRI) scans in research involving human subjects in the Florida International University (FIU) Center for Imaging Science (CIS).

BACKGROUND

MRI scans are among the imaging technologies used in research at the center. MRI scans undertaken for research purposes are not intended for use as diagnostic or therapeutic purposes. The CIS does not have medical or radiological staff that interprets MRI scans, thus no information regarding normal or abnormal findings will be routinely provided by CIS staff to research subjects or their physicians.

Occasional variations from expected brain morphology can be seen in many research participants undergoing MRI scans. In light of such variations, and given the rapidly increasing number of research MRIs conducted, significant ethical questions about responsibilities and procedures for detecting and disclosing incidental findings have been raised. Variations from normal morphology may or may not have medical implications.

There is no regulatory requirement to have every research scan read by an outside radiologist. However, in recognition of the fact that, on occasion, incidental findings may need to be investigated medically, and in a best-faith effort to inform research participants of that possibility, the policy of the CIS is to have all structural scans of research subjects reviewed by a radiologist.

Research participants will be provided with a DVD copy of their structural data obtained during the study in cases where a radiologist has determined that there is a finding that might be important to the participant's health.

IRB APPROVAL

All FIU investigators conducting human subjects research who plan to use the CIS must obtain FIU IRB approval for their research protocol (except for cases where an agreement allows for FIU to defer approval to an external IRB). All external non-FIU investigators conducting human subjects (for studies in which FIU is not engaged in conducting the research and FIU is not a source for recruitment) who plan to use the CIS are required to obtain IRB approval for their research protocol from their own institution. Under no circumstances will an investigator be allowed to use the facility for research purposes without submitting a copy of their IRB approved protocol, IRB approved consent form, and IRB approval letter.

IRB approval must be granted prior to submitting a request for project approval and scan time to the CIS MRI facility. Ongoing projects will be suspended when IRB approval expires. PIs must provide written documentation of the initial IRB approval and annual IRB renewal. The PI must make sure that the protocols list all personnel who will be conducting MRI research. All IRB approved protocols must include the MR Physicist and all MR Technicians as Protocol Associates. These personnel should be listed as Key Associates who are involved in Screening and Data Collection. Please contact the Lead MR Technician to obtain each individual's Panther ID as well as their CITI IRB training certificate.

REQUIRED LANGUAGE FOR INFORMED CONSENT

Standard language relating to MRI risks and incidental findings is required for all study consent and assent forms involving MRI scans. Researchers are required to use the MRI informed consent templates located on the following page: <http://research.fiu.edu/irb/informed-consent-templates>.

INCIDENTAL FINDINGS AND INTERPRETATION OF SCANS

Under no circumstances may an investigator, research staff, or the imaging center staff interpret scans as normal or abnormal. All scans performed at the CIS are for research purposes only and are NOT intended for clinical diagnoses or therapeutic purposes. However, in recognition of the fact that, on occasion, incidental findings may need to be investigated medically, and in a best faith effort to inform research subjects of that possibility, the policy of having all structural scans of normal research subjects by a radiologist has been implemented.

All structural scans will be sent for expert radiological review, which will be provided, by contractual agreement with the Radiology Associates of South Florida (unless circumstances require that a particular project utilize a different organization for the radiological reviews). If an investigator would like to request an exception to this requirement for participants with a pre-diagnosed condition, this can be requested in the IRB protocol application.

The scans will be provided to the radiologists without identifying data. Scans will solely contain the participant identifying number, gender and age of the subject. In the unlikely event that the team of radiologists identifies an incidental finding, the researcher will inform the subject and will provide a referral for follow-up. The CIS staff will **not** be involved in any medical interaction with the subject.

Subjects who are part of repeated scanning for multiple studies, will have their scans reviewed after their first scanning session. If their participation continues for over one year, the first scan performed one year after the previously reviewed scan will be sent for review. Investigators will be required to identify such subjects.

Research participants will be provided with a DVD copy of their structural data obtained during the study in cases where a radiologist has determined that there is a finding that might be important to the participant's health. The research participant may decline from receiving a DVD copy. A DVD copy will also be made available to any research participant upon his/her request.