

Appendix VII: Policy Concerning Human Subjects Research at the Center for Cognitive and Behavioral Brain Imaging

SCOPE:

This policy establishes procedures for the handling of structural MR scans in research involving human subjects in the Center for Cognitive and Behavioral Brain Imaging.

BACKGROUND:

The Center for Cognitive and Behavioral Brain Imaging is a research facility at Ohio State University. The Center for Cognitive and Behavioral Brain Imaging is part of the College of Arts & Sciences, and is not affiliated with the medical school or the university hospital. Structural Magnetic Resonance Imaging (MRI) Scans are among the imaging technologies used in research at the center. As with the other imaging done at this center, MRI scans are undertaken for research purposes only and not for diagnostic or therapeutic purposes. The Center for Cognitive and Behavioral Brain Imaging does not have medical or radiological staff that interprets MRI scans, thus no information regarding normal or abnormal findings will be routinely provided to research subjects or their physicians.

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 may or may not have medical implications.

The Center for Cognitive and Behavioral Brain Imaging, a non-medical facility, has established the following policy for structural MRI scans obtained for research purposes:

All human research protocols undertaken at the Center for Cognitive and Behavioral Brain Imaging shall include in the IRB application an explicit description of the procedure for handling all findings, including incidental

findings.

The informed consent document shall contain an explicit description of the limits of communication with the subject with respect to scan findings and follow up responsibilities.

All subjects have the right to be informed of the strengths and limitations of the research team in identifying, interpreting, or communicating findings.

There is no national requirement to have every research scan read by an outside neuroradiologist.

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 the Center for Cognitive and Behavioral Brain Imaging is to have all structural scans of normal research subjects reviewed by a neuroradiologist. [See below policy for subjects with known brain damage].

For the time being, the costs of the service will be supported by the Center.

For studied involving subject without any known brain damage, you may offer them a CD copy of the structural data obtained during the study, for their use. This offer serves to assure subjects that their scan is not afforded unique treatment due to detection of any incidental findings. Subjects may decline this offer.

IRB APPROVAL

All investigators conducting human subjects research who plan to use the Center for Cognitive and Behavioral Brain Imaging must obtain IRB approval for their research protocol. Under no circumstances will such an investigator be allowed to use the facility without submitting proof of IRB approval.

Mandatory Language for Informed Consents:

“The magnetic resonance imaging (MRI) scan you will receive during the course of this study is for research purposes only. It is not a clinical scan intended for diagnostic or therapeutic purposes. The Center for Cognitive and Behavioral Brain Imaging is a research center. It is NOT a Clinical MRI facility in a hospital. There are no neuroradiologists at the Center for Cognitive and Behavioral Brain Imaging, therefore the staff are unable to make any medical comments about your scan. Should you want to know if your scan is normal or abnormal, the staff will not be able to tell you. However, all structural scans obtained in normal research subjects are sent to a Neuroradiologist for blind review. In the rare event the neuroradiologist detects an abnormality he will be given your name and contact, or that of a physician of your choice, so he can explain and discuss the finding with you. You will also be given the data of the structural images on a CD so you can consult with your physician. You may decline this offer.”

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 Center for Cognitive and Behavioral Brain Imaging 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 scans of normal research subjects by a neroradiologist has been implemented.

Every normal subject studied at the Center for Cognitive and Behavioral Brain Imaging will have, in addition to the structural MRI performed as part of the study, a brief T2 weighted sequence (2 minutes). This data will be sent for expert neuroradiological review, which will be provided, by contractual agreement between Center for Cognitive and Behavioral Brain Imaging and Nationwide Children’s Hospital at Columbus, Ohio, by neuroradiologists at Nationwide Children’s Hospital Columbus.

This policy must be included in the Consent Form (a sample is provided in the end of this document). The language in the consent form allows the subject to choose if she/he wants the neuroradiologist to contact her/him or a physician of her/his choice in the event of an incidental finding.

The scans will be provided to the neuroradiologists by Deborah Hardesty without identifying data. Scans will solely contain the CCBBI identifying number, gender and age of the subject. In the unlikely event that the team of neuroradiologists identifies an incidental finding, Deborah Hardesty will be asked to provide the subject's name and contact, as well as his/her physician's name and contact. The neuroradiologists will, at that time, inform us that the subject is not appropriate for research and will take it upon himself to contact the subject/physician and discuss the finding and any further action to be taken, if necessary. The Center for Cognitive and Behavioral Brain Imaging will **not** be involved in any medical interaction with the subject and will **not** be informed of any medical diagnosis. Deborah Hardesty will simply inform the respective PI/investigator identified on the forms signed prior to scanning, as soon as neuroradiologists report that a subject is not appropriate for research.

There are two exceptions to the above mentioned policy:

1. 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. We need your cooperation in identifying such subjects.
2. Subjects with known brain diseases who are part of structural/functional MR protocols will not have their scans sent to neuroradiologists for review and should therefore not sign the attached document.

Investigators who will use brain damaged subjects in research protocols should follow the policy of providing the structural scan to the subjects' physician.

CDs with the structural images are offered to the participants so that, those who wish can consult directly with their own medical practitioner.