

## **Appendix VII. Policy Concerning Human Subjects Research at the Dana & David Dornsife Cognitive Neuroscience Imaging center**

### **SCOPE:**

This policy establishes Dana & David Dornsife Cognitive Neuroscience Imaging center (DNI) procedures for the handling of structural MR scans in research involving human subjects.

### **BACKGROUND:**

The Dana & David Dornsife Cognitive Neuroscience Imaging center is a research facility located at the University of Southern California's University Park Campus. The Dornsife imaging center is part of the College of Letters, Arts & Sciences, and is not affiliated with the Keck School of Medicine or the University Hospital. Structural Magnetic Resonance Imaging (MRI) scans are among the imaging technologies used in research at the center. As with other imaging done at this center, MRI scans are undertaken for research purposes only and not for diagnostic or therapeutic purposes. The Dornsife imaging 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 subjects by Dornsife research staff.

Occasional variations from expected brain morphology can be seen in 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.

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

All subjects must be made aware that Dornsife staff does not have the requisite expertise to identify, interpret or communicate neurological findings for diagnosis or treatment.

While there is no national requirement to have every research scan read by an outside neuroradiologist, the Dornsife imaging center has contracted to have all structural scans of normal research subjects reviewed by a neuroradiologist. [See below for additional information about procedures for subjects with known brain damage]. The cost of the service is currently supported by the Dornsife imaging center.

All subjects participating in MRI research projects shall be offered a CD copy of the structural data obtained during the study. 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 Dornsife imaging center must obtain IRB approval for their research protocol. 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 accessible here:

[www.usc.edu/admin/opr/private/docs/upirb/forms/General\\_ICF\\_Updated\\_06202012.doc](http://www.usc.edu/admin/opr/private/docs/upirb/forms/General_ICF_Updated_06202012.doc).

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

A copy of the Dornsife Imaging center mandatory language is provided below:

“The Dornsife Imaging Center is a research unit, not a clinical/diagnostic MRI center. The MRI scans obtained at the Dornsife Imaging Center, such as the scan you are about to undergo, are research scans. They are not meant to provide clinical/diagnostic information. Most scans performed in normal human subjects are routine and without abnormalities. However, on occasion, though rarely, something abnormal may be present. These rare occurrences are called incidental findings.

Because the Dornsife Imaging Center **is not** a clinical/diagnostic center, the DNI has no neuroradiologist staff members (medical doctors who can comment on MRI scans), and therefore we cannot tell if your scan shows or does not show any abnormality.

Because detecting and investigating such potential abnormalities may be relevant to your health, the Dornsife Imaging Center established a partnership with University Children Medical Group Inc., where a neuroradiologist (Dr. Marvin Nelson or one of his colleagues) will review the structural scans that are part of the research scans obtained at the Dornsife Center. If they detect any image that suggests an abnormality, they will contact you or a physician of your choice, to inform about the findings and suggest further evaluation if needed.

In case you are planning to obtain or change your health insurance coverage in the future, you must be aware that in the unlikely event an incidental finding is detected, this might be construed as a “pre-existing condition” by the new health care provider/insurer. For that reason, and in case you do not want to be informed about any potential incidental finding, you may elect to NOT take part in this study. In case you agree to participate in this study your identity, along with your physician’s identity and contact information, will only be disclosed to Dr. Nelson should he need to contact you. By agreeing to participate in this study you also agree to having Dr. Nelson (or one of his associates) contact you, or the physician of your choice, about any incidental finding deemed to be important to your health. You will be asked to provide your and your physician’s contact information on a separate sheet.

You will also be given the data of the structural images on a CD so you can further consult with your physician. You may decline the offer of receiving the images on a CD.”

## 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 Dornsife imaging center 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 is that all scans of normal research subjects will be read by a neuroradiologist.

Every normal subject studied at the Dornsife imaging center will have, in addition to the structural MRI performed as part of the study, a brief T2 weighted sequence (2 minutes). These data will be sent for neuroradiological review, provided by contractual agreement between DNI/USC and Dr. Marvin Nelson's team of neuroradiologists at Childrens Hospital of Los Angeles Medical Group (CHLAMG).

Normal subjects will be informed of the neuroradiology review policy and will have to read and sign an (IRB approved) agreement (see below), prior to being scanned. The document allows the subject to opt out of the neuroradiology scan review, in which case the subject will not be scanned. In other words, subjects who agree to participate in a study but do not accept the scan review will be excluded from the study. The neuroradiologist review is an ethical approach to identify and inform subjects of any incidental finding that, though rare, may be detected.

Dornsife staff will provide scans to Dr. Nelson without personally identifying data. Scans will contain solely the DNI identifying number, gender and age of the subject. In the unlikely event that Dr. Nelson's team identifies an incidental finding, Dornsife staff will be asked to provide the subject's name and contact information, as well as his/her physician's name and contact information to Dr. Nelson. Dr Nelson will, at that time, inform DNI that the subject is not appropriate for research and will take it upon himself to contact the subject/physician and discuss the finding and suggest further action. The DNI will **not** be involved in any medical interaction with the subject and will **not** be informed of any medical diagnosis. Dornsife staff will simply inform the respective PI/investigator as soon as Dr. Nelson reports that a subject is not appropriate for research.

There is a fee for this neurological service which, for the time being, will be absorbed by the DNI. Scans will be sent to Dr. Nelson at regular intervals.

There are 2 exceptions to the above mentioned policy:

1. Subjects who are part of repeated scanning for multiple studies, will have their scans reviewed only after their first scanning session. If participation continues for over a year, the next scan performed one year after the previously reviewed scan will be sent for review. We need faculty cooperation in identifying such subjects. DNI does not keep a roster of those scanned.

2. Subjects with known brain disease who are part of structural/functional MR protocols will not have their scans sent to Dr. Nelson for review and should therefore not sign the attached document. Investigators who use known brain damaged subjects in research protocols should follow the practice of providing the structural scan to the subjects' physician.

## **DNI SUBJECT AGREEMENT**

**(All normal subjects must sign both DNI Subject Agreement and study-specific informed consent documents.)**

### **DNI Subject Agreement**

You have agreed to be a research subject in a study by Dr. (name of PI) \_\_\_\_\_ for which a Magnetic Resonance Imaging (MRI) scan is going to be performed. Please read the following policy of the Dornsife Imaging center with regard to MRI scans. You may ask any questions before we start the scan.

The Dornsife imaging center is a research unit, not a clinical/diagnostic MRI center. The MRI scans obtained at the Dornsife imaging center, such as the scan you are about to undergo, are research scans. They are not meant to provide clinical/diagnostic information.

Most scans performed in normal human subjects are routine and without abnormalities. However, on occasion, though rarely, something abnormal may be present. These rare occurrences are called incidental findings.

Because the Dornsife imaging center **is not** a clinical/diagnostic center, the DNI has no neuroradiologist staff members (medical doctors who can comment on MRI scans), and therefore we cannot tell if your scan shows or does not show any abnormality.

Because detecting and investigating such potential abnormalities may be relevant to your health, the Dornsife imaging center established a partnership with Children's Hospital Los Angeles Medical Group Inc., where a neuroradiologist (Dr. Marvin Nelson or one of his colleagues) will review the structural scans that are part of the research scans obtained at the Dornsife imaging center. If they detect any image that suggests an abnormality, they will contact you or a physician of your choice, to inform you about the findings and suggest further evaluation if needed.

In case you are planning to obtain or change your health insurance coverage in the future, you must be aware that in the unlikely event an incidental finding is detected, this might be construed as a "pre-existing condition" by the new health care provider/insurer. For that reason, you may elect NOT to take part in this study.

Your identity, along with your physician's identity, will only be disclosed to Dr. Nelson should he need to contact you.

I have read and understand the text above and its implications, and agree to participate in the research. In the rare event that incidental finding is detected in my MRI scan, I agree to DNI policy to have the information and results provided to me/my physician

Your signature ..... Date .... / .... / .....

Signature of Dornsife Center Staff ..... Date .... / .... / .....

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Please provide:

**Your Name** ..... cell/phone number .....

Your email address .....

**Name of your physician/health care provider** .....

Cell/phone number .....