# Policy Concerning Human Subjects Research at Cognitive Neuroimaging center (CoNiC)

**SCOPE:**

This policy establishes procedures for the handling of structural MR scans in research involving human subjects in the Center for Cognitive Neuroimaging center (CoNiC).

# BACKGROUND:

The Center for Cognitive Neuroimaging center (CoNiC) is a research facility at Experimental medicine Building, Level 7, LKCMedicine, Nanyang Technological University, Singapore. The Center for Cognitive Neuroimaging center (CoNiC) is not affiliated with the 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 Neuroimaging center (CoNiC) 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 Neuroimaging center (CoNiC), 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 Neuroimaging center (CoNiC) 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 Neuroimaging center (CoNiC) is to have all structural scans of normal research subjects reviewed by a neuroradiologist. [See below policy for subjects with known brain damage].

The costs of the service will not be supported by the Center. For any further investigation after the incidental findings the subjects have to bear their own cost. All subjects need to fill in the consent form and duly sign in the presence of the center staff.

# IRB APPROVAL

All investigators conducting human subject’s research who plan to use the Center for Cognitive Neuroimaging center (CoNiC) 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.

**Consent form for incidental findings**

*I would like to be informed of:*

Any finding that may require any further investigations

I’m aware that after the incidental findings Cognitive Neuroimaging Center at NTU CoNiC will not bear any cost for further investigation and all I will undertake all responsibility to cover all the expenses for further investigation and Treatment

In case of any incidental findings I would like to choose the following options

 CoNiC will send the findings to radiologist and I will pay for all the further investigations.

 CoNiC will advise my General practitioner to the address given below and I will undertake the referral charges if any.

 Doctor Name:

 Address:

 Phone:

I declare that I do not have any medical conditions to my knowledge and I’m not undergoing any treatment.

Signature of the subject:

 Name of the subject:

 NRIC/Fin/passport number:

 Address, Phone number and Email:

Witness: