
OFFICE MEMO

POLICY for Management of Incidental Findings on Research MRI Scans in the Center for Advanced Brain Imaging at NKI

A. Responsibilities Upon Detection:

1. All Individuals who collect MRI scans within CABI, and all individuals who review such scans (the principal investigator, a collaborating investigator or image analysis technicians) must be familiar with and agree to comply with the policies stated in this document.
2. In the course of collecting an MRI scan, through initial review of an MRI scan or post-collection review of an MRI scan, any notice of a potential abnormality must be followed by professional assessment of the finding (i.e., by a Radiologist). Following the detection, a determination of whether or not it is necessary to inform the subject must be made by the Radiologist. The operant assumption in this policy is that *if something is noticed, it cannot be ignored.*

B. Evaluation Procedure to be followed when an abnormality is identified:

1. The individual making the discovery will complete a confidential 'MRI Detection Form', which includes a description of the MRI scan, a description of the finding, and the relevant identifying information to permit locating the finding in the recorded data. The PI will co-sign the *MRI detection Form*. The form will include the date of the scan and the date that the form was completed.
2. The MRI scan in question will be transferred to a CD in DICOM format, labeled with the date of the scan, the subjects name, the principal investigators name and the study ID and given to the CABI chief technician. The CD will be saved along with written documentation as defined below.

C. Review Procedure once the abnormality is identified:

1. The Radiologist will be notified by email or phone by Mr. Sangoi that review of a Research Scan has been requested, and the CD and MRI Detection form will be delivered to the Radiologist. This request should be placed within one week of the scan date.
2. Upon review, the Radiologist will complete appropriate sections of the *MRI Detection Form* and indicate what, if any, course of action should be taken.
 - a. If the Radiologist determines that the finding is not significant, a notation to that effect will be made, and the procedure terminated. The Radiologist and Mr. Sangoi will co-sign the form, and the CD and signed and terminated MRI Detection Form filed in the CABI.
 - b. If the Radiologist determines that the finding requires follow-up, a notation to that effect will be made on the *MRI Detection Form*, and the subject notification process will be initiated.
 - c. Both the Completed *MRI Detection Form* and the CD will be returned to Mr. Sangoi
3. The Chief MR Technician, will initiate subject Notification. The MR Technician will complete the written documentation (*Notification of Finding*) which will include:
 - d. The standardized statement that a finding was made.
 - e. The Radiologist's statement of the findings significance.
 - f. A statement of what follow-up, if any, was deemed necessary, including the need to contact their primary physician and obtain a clinical scan to confirm the finding.
 - g. Identify on the form the date, time and individual who notified the patient of the finding, if required.
 - h. If possible, the signature of the patient will be obtained acknowledging that they received notification AND recommendations for further follow-up. If the patient cannot be notified by phone or in person, then the report will be provided via registered mail.

D. Notification Procedure

- i. The Principal Investigator will be required to contact the subject and notify them of the finding as well as the consequent process of review, and the need for a clinical scan. The date and time of this contact will be indicated on the *Notification of Finding*, with the PI's signature. The subject will be provided with the written *Notification of Finding* and if requested a copy of



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the CD, which can either be picked up by the subject or mailed to the subject, at the subject's discretion. If the patient cannot be contacted as specified above, then the patient will be notified by the Investigator via registered mail within one week of the finding. The signature of the Contact Person and the Principal Investigator will be obtained indicating that these actions have taken place.

E. Quality Control

At each annual review of the IDE, a review of the process for each of incidental finding instance will be initiated to ensure proper procedures are followed to completion.

F. Investigator Cautions

1. The individual contacting the subject will be informed NOT to show subjects their imaging abnormalities or speculate about the significance of findings
2. Unless directly requested by the patient, Investigators may not discuss the subject's imaging abnormalities or speculate about the significance of findings with any other individual than those specified in this policy. If the patient does request that the investigator discuss the finding with another physician or family member, a HIPPA wavier will be obtained before proceeding.
3. The Investigator will not discuss the significance of the imaging abnormality with the subject in a manner that is not consistent with their medical expertise.