Title: MRI Incidental Findings	
Date First Created: June 2009	**Date Revised: November 2020**
Approved By: (Terminal Committee) Research Management Committee	**Editor: Jean Lazarus**

1.0 Policy Statement

To specify the procedure for handling incidental findings associated with functional MRI experiments and dissemination of MRI scans.

2.0 Definitions

Incidental Findings - As structural MRIs are collected at the same time as our functional scans, it is possible that abnormalities will be noted on the structural scan from a volunteer.

3.0 Background and Scope

1. MRI scans conducted for research at Baycrest are not intended for diagnostic, clinical or medical use.
2. Research participants receiving an MRI scan will be informed of the possibility of incidental findings.
3. Research participants must consent in advance of their participation to review of the research scan by a qualified health professional for clarification of suspected incidental findings.
4. The participant will be assisted in procuring appropriate medical follow-up so that an appropriate clinician can disclose the incidental findings.

4.0 Procedure

1. The following disclaimer will appear on all consent forms:

   The MRI scan being done is designed to answer research questions, not to examine your brain medically. This MRI scan is not a substitute for one that a doctor would order, and it may not show problems that would be picked up by a medical MRI scan. However, in the unlikely event that we note an atypical finding on your MRI scan, we will contact you to help you arrange medical follow-up to interpret the significance of the findings, if any. We may also ask a radiologist, or other health professionals, to look at your scan, and by signing this consent form

you agree to the release of the scan for review. It is possible that you could be unnecessarily worried if a problem were suspected, but not actually found.

2. If incidental findings are noted on the MRI, all investigators will follow the procedure outlined below:

    a. The MRI technologist will view each structural MRI obtained and, if a brain abnormality is noted that clearly would exclude the participant from the study (e.g., an obvious tumor), the technologist will stop the study. The participant will be told that the study has been completed “according to the protocol”, thanked and paid the full reimbursement for time. If the volunteer asks to see the scans, he/she should be told that a physician with training to read the scans should be there to interpret them and one is not available. The volunteer can be told that the Primary Investigator will discuss the scan with him/her at a later time.

    b. For all studies, whether completed or not, if the technologist thinks that the scan may have an incidental finding, he or she will send the scan to a radiologist who will provide a recommendation for follow-up (this will NOT be an official report). The technologist will notify, via email, the Principal Investigator (PI) on the project as soon as possible (i.e., the scientist associated with the project, not the student or postdoc).

    c. The Participant Coordinator Office will be copied on the message sent to the PI. The Coordinator will make a note in the person’s database file noting that this person is likely not suitable as a healthy volunteer but might be acceptable for other studies. Other investigators for studies in which the subject participated will also be notified. The Participant Coordinator will ensure that the procedure outlined below is followed in a timely manner and will provide assistance to the Primary Investigator when necessary.

    d. The Principle Investigatorβ will contact the participant or designated decision maker by telephone, and will read the following prepared script:

        We detected some brain findings on your MRI scan. [IF SCAN WAS TERMINATED: It is our policy to stop the scanning when this occurs.] It is not clear whether the findings seen on the images are medically significant. It is not unusual for findings to emerge in a research study, and many of them are not significant, so I do not want you to become unnecessarily alarmed. Nonetheless, we recommend that you have a consultation with a specialist to determine the importance, if any, of the findings on your scan. As the scan that we obtained is not diagnostic, you will need to have a clinical MRI for a full evaluation. We can make an appointment for you to see one of Baycrest’s Brain Health Centre Clinic neurologists, but need a referral from your doctor to proceed. Alternatively, you may obtain a referral to a neurologist chosen by your family physician. If you are willing, Brain Health Centre Clinic staff will contact your doctor to obtain this referral. You can decide not to pursue this, but it is our policy to make this information available to you.

        βNB: The Principle Investigator must contact the participant; it cannot be delegated to study or lab personnel..

e. If the participant wishes to be seen in the Baycrest clinic, the Primary Investigator will obtain verbal consent from the participant, and document this consent (a consent form will be provided that will be filled out at the time of the contact). A formal letter will be sent to the participant re-iterating the information provided at the time of the phone call and including any new information that is pertinent (e.g., that the process of setting up an appointment at the clinic has been initiated). A template for such a letter can be obtained from the subject coordinator. Whatever the participant decides to do (e.g, whether or not to be seen in the Baycrest clinic), this should be written on a separate form filled out at the time of contact.

f. The Primary Investigator should verify the person's home address, date of birth, and telephone number.

g. If verbal consent is obtained, the Primary Investigator may share the research scan obtained at Baycrest with one of the BHCC full-time neurologists.

h. The Primary Investigator will notify the BHCC scheduling staff, who will contact the participant's physician and obtain a referral.

i. An appointment will be made with a clinic neurologist as soon as possible.

j. The Participant Coordinator Office will be notified as to the action taken, and this will be documented in the participant database.

k. The neurologist will meet with the participant as scheduled, and advise whether any additional follow-up is required.

Note: The above procedure applies to research with volunteers for whom there is no known medical condition. All projects involving patients MUST have a physician (typically a neurologist) as a collaborator or co-investigator. In that case the neurologist would review all scans with the PI either monthly, or more frequently, at the discretion of the PI, and initiate follow-up of incidental findings if necessary.

3. Dissemination of MRI incidental scans
    a. Copies of scans will not be routinely provided to participants.

    b. If a participant asks for copies of the scan to be sent to his/her physician for any reason, such copies will be provided. This will typically be in electronic form (e.g., a DVD created by the fMRI technologist) that contains software so that the scan may be viewed on the physician's computer.

        i. A letter will accompany the copies clearly stating that the scans are not of diagnostic quality and should not be used as a substitute for a clinical scan.
        ii. Along with the MRI scan and letter, a copy of the research-affiliated radiologist's comments about the scan can be forwarded to the physician at his/her request. It should be noted that these comments do not constitute an official report

5.0 Cross Reference Policies/Documents

N/A.

Approval:
Research Management Committee

6.0 Appendices/Links

N/A