Western Centre for Functional and Metabolic Mapping

3T/7T MRI FACILITY

SOP Number:	**230.03**
Title	**Incidental Findings**

Revision Chronology		
Version Number	**Date**	**Changes**
230.01	**1 March 2010**	**First version**
230.02	**25 August 2011**	**Wording revised for clarity in section 2.2, section 2.3 added.**
230.03	**31 January 2013**	**Sections 2 & 3 renamed, revisions throughout.**

Facility Manager Signature: _____

Date: _____

ROBARTS RESEARCH INSTITUTE

CENTRE FOR FUNCTIONAL AND METABOLIC MAPPING
3T/7T MRI FACILITY

Standard Operating Procedure #230.03

Incidental Findings

1. Introduction

1.1. The 3T/7T MRI Facility is used primarily for *in-vivo* studies of human and animal structure and function. These studies include assessment of metabolism and physiology, cognitive function and vascular dynamics, not only in normal and research patient populations, but also in *in-vitro* and animal models using a variety of advanced nuclear magnetic resonance imaging and spectroscopy techniques. The 3T/7T Facility represents a unique national resource for state-of-the-art evaluation of structure and functional activity using a variety of MRI and MRS techniques in a research setting. The facility resources are available to peer-reviewed grant funded scientific collaborators with appropriate Review Ethics Board (REB) protocols in place, see SOP#210: "New Protocols and Ethics".

1.2. Extensive training is required before performing any procedure on the 3T MRI system, see SOP#130: "MRI Personnel Training".

1.3. Incidental findings are defined as previously undiagnosed medical conditions that are discovered unintentionally and are unrelated to the current medical condition or reason for which the individual is being treated or undergoing imaging. Research MRI scans are a leading source of incidental findings. A recent study reported that 2.2% of research MRI brain scans yielded an incidental finding.[1]

[1] *Orme NM, Fletcher JG, Siddiki HA, et al. Incidental Findings in Imaging Research: Evaluating Incidence, Benefit, and Burden. Arch Intern Med. 2010;170(17):1525-1532.*

1.4. The 3T/7T MRI Facility staff are not trained or qualified to detect or diagnose pathologies, and a radiologist does not routinely review acquired images. Research MRI protocols generally do not include a full suite of clinical acquisitions, further limiting our ability to detect abnormalities. Our detection ability is therefore limited to the research protocol and to the training and experience of the MRI Technologists/Operators and study investigators. An incidental finding may be detected either at the time the scan is collected or by investigators at a later time. It is both the operators' and the investigators' ethical responsibility to report and follow up on any abnormalities detected.

2. Incidental Findings: Facility and Staff Responsibilities

2.1 If the MRI Technologist/Operator notes an abnormality during the scan session, care should be taken to avoid alarming the volunteer or patient. The acquisition of additional scans should be avoided, unless the Technologist/Operator deems it appropriate and necessary to confirm or rule out the presence of an abnormality.

2.2 Upon completion of the scan session, MRI Operators should report their findings to the Facility Manager or an MRI Technologist, who will then review the images to try to confirm the presence or absence of an abnormality.

2.3 If an incidental finding is confirmed, the Facility Manager or MRI Technologist will then notify the Principle Investigator of the finding.

2.4 Clinical radiology reports of research scans conducted in the 3T/7T MRI Facility will NOT be issued unless they are requested via the procedure listed in Section 3.4 below.

2.5 Additional MRI scans will not be performed by our facility to follow up on incidental findings.

3. Incidental Findings: Principle Investigator Responsibilities

3.1 If the MRI Technologist/Operator detects an incidental finding, the Principle Investigator (PI) of the study will be notified. Alternatively, the PI's research staff may identify an incidental finding at a later time and notify the PI of their finding.

3.2 If an investigator or their research staff detect an abnormality in a research subject's MR images but are unsure whether it is significant, they may request the Facility Manager or MRI Technologist to review the images to assist them in determining whether or not the subject should be notified of an incidental finding.

3.3 Once the PI has been made aware of an incidental finding, it is their responsibility to follow-up with the patient/volunteer and notify them of the finding.

3.3.1 Care should be taken to avoid unnecessarily alarming the individual, and terminology should be kept general and non-descriptive (i.e. "incidental finding" or "possible abnormality" rather than "brain tumor", "lesion", or "region of hyperintensity"). Keep in mind that we are not qualified to diagnose pathologies, and cannot determine the significance of any abnormality detected.

3.4 The PI should contact the patient/volunteer directly to inform them that an incidental finding has been identified and advise them of their options for follow-up, which include the following:

3.4.1 If the Principle Investigator IS an **LHSC Physician**:

3.4.1.1 With the patient/volunteer's permission, the PI may supply the anatomical images directly to LHSC radiology along with a request for a "review of guest exam" through the internal system.

3.4.1.2 A radiologist will review the images, and a report will be sent directly to the subject's family physician. The report will detail the findings and whether any additional imaging or investigation is necessary, as well as the urgency of it, which the subject can follow up on with their family physician.

3.4.2 If the Principle Investigator is NOT an **LHSC Physician**:

3.4.2.1 The PI should recommend that the subject contact their family physician to notify them that an incidental finding was detected on a research MRI scan.

3.4.2.2 The PI may provide them with a copy of their anatomical images on a CD/DVD to give to their physician.

3.4.2.3 Family physicians and non-LHSC physicians can submit the images to LHSC radiology along with a request for a "review of guest exam".

3.4.2.4 A radiologist will review the images, and a report will be sent directly to the subject's family physician. The report will detail the findings and

whether any additional imaging or investigation is necessary, as well as the urgency of it, which the subject can follow up on with their family physician.

3.5 If the patient/volunteer does not have a family physician, the subject may be provided with a copy of their anatomical images on CD/DVD, which can be taken to any walk-in clinic or to Staff or Student Health Services on campus. The subject should inform the physician that they participated in a research MRI scan and were informed of a potential incidental finding that requires follow up. The physician can then forward the images to LHSC radiology with a request for a "review of guest exam", and the report detailing the findings will be returned to the clinic.

3.6 Note that many family physicians are unsure how to submit the "review of guest exam" request, and may instead opt to order a clinical MRI scan. This decision is at the discretion of the physician; however, providing your patient/volunteer with a copy of their anatomical images on a CD/DVD as well as a printout with the instructions in Section 3.4 above may assist them in this process and help avoid unnecessary clinical MRI scans from being ordered.

3.7 Investigators should avoid publishing images obtained from subjects identified as having incidental findings.

3.8 Primary investigators and the 3T/7T MRI Facility are not responsible for incidental findings that are detected, pathologies that may be present but are not detected, the effect or outcome of an incidental finding on the patient/volunteer, or for any costs that may be incurred by the patient/volunteer during the follow up or treatment of an incidental finding. By participating in a research MRI study, individuals are agreeing to the possibility of an incidental finding being discovered. If a participant does not agree to the potential risk of discovering an incidental finding they should not participate in the study.