



3T/7T MRI FACILITY

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| SOP Number: | 350.01 |
| Title | Incidental Findings |

| Revision Chronology | | |
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| Version Number | Date | Changes |
| 350.01 | 1 March 2010 | First version |
| 350.01 | 25 Aug 2011 | Wording revised for clarity in section 2.2, section 2.3 added. |
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Facility Manager Signature: _____

Date: _____

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

Standard Operating Procedure #350.01

Incidental Findings Protocol

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#130-01: "New Protocols and Ethics".
- 1.2. Training is required to perform any procedure on the MRI system. See SOP #120-01: "Safety and Operator Training Procedures".
- 1.3. Our operators are not trained or qualified to detect or diagnose pathologies, and a radiologist does not review acquired images. Therefore our ability to detect abnormalities is limited by the training and experience of the MRI operators and study investigators. An incidental finding may be detected either at the time the scan is collected or may be identified 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

- 2.1. If an abnormality is noted by the scan operator during the scan session:
 - 2.1.1. Extreme care should be taken to avoid alarming the volunteer or patient subject. The acquisition of special additional scans should be avoided, unless the operator deems it appropriate and necessary to confirm or rule out the presence of an abnormality.
 - 2.1.2. Upon completion of the scan session, operators should report their findings to the Head MRI Technologist, who will review the images to confirm the presence of an abnormality.
 - 2.1.3. The Head MRI Technologist will notify the Principle Investigator (PI) of the incidental finding.
- 2.2. Once the PI had been notified of an incidental finding, it is their responsibility to follow-up on the finding via the procedure outlined below [2.2.1].
 - 2.2.1. The PI should contact the subject directly to inform them that an incidental finding has been identified and advise them of their options for follow-up, which may include the following:
 - 2.2.1.1. If the Principle Investigator IS an LHSC Physician:

2.2.1.1.1. With the subject's permission, the PI may supply the anatomical images directly to radiology and request a "review of guest exam" through the internal system, with the report to be sent to the subject's family physician. Radiology will issue a report detailing 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 personal physician.

2.2.1.2. If the Principle Investigator is NOT an LHSC Physician:

2.2.1.2.1. The PI can recommend that the subject should see or contact their family physician to notify them that an incidental finding was detected on a research MRI scan conducted. The PI may provide them with a copy of their anatomical images to give to their physician. Family physicians and non-LHSC physicians can submit the images to radiology with a request for them to be reviewed (a "review of guest exam"). Radiology will issue a report directly to the family physician detailing the findings and whether any additional imaging or investigation is necessary.

2.2.1.3. If the subject does not have a family physician, the subject may be provided with a copy of their anatomical images 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 which requires follow up. That physician can forward the images to radiology with a request for a "review of guest exam", and the report detailing the findings will be returned to that clinic.

2.2.2. Investigators should not publish images obtained from subjects identified as having incidental findings.

2.2.3. Clinical radiology reports of research scans conducted in the 3T/7T facility will not be issued unless they are requested via the procedure listed in section [2.2.1]. Clinical MR scans will not be performed by our facility to follow up on incidental findings.

2.3. Investigators and the facility are not responsible for incidental findings, the outcome of medical follow-up on incidental findings, or for any costs that may be incurred during medical follow-up. By participating in a research MRI scan, individuals are agreeing to the possibility of being informed about a potential incidental finding, according to the above-described procedure. If a participant does not agree to the potential risk of discovering an incidental finding they should not participate in the study.