SOP Number:	**225.12**	
Title:	**Incidental Pathological Findings**	
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Directors Signature: _____ Date: 2023/SEP/01

1. SCOPE

This SOP describes the procedure for reporting incidental pathological findings.

2. PROCEDURES

The 3T MRI facility staff are not trained or qualified to detect or diagnose pathological findings. The facility does not have an in-house radiologist to routinely review images, and research MRI protocols generally do not include a full set of clinical images, which limits the ability to properly detect abnormalities. Therefore, the detection ability is limited to the research protocol and to the training, experience of the MRI technologist, and study investigators.

An incidental finding may be detected either at the time the scan is collected or by research personnel at a later time (during image review). It is both the MRI technologist's and investigator's responsibility to report and follow up on any abnormalities detected.

a. Procedure for reporting incidental pathological findings: Facility and Staff Responsibilities

- If the MRI technologist confirms any abnormality during the scan:
  - Care should be taken to avoid alarming the volunteer or patient.
  - Additional scan acquisitions should be avoided unless the MRI technologist deems it necessary to confirm or rule out the presence of an abnormality.
  - If an incidental finding is confirmed, the MRI technologist will notify the principal investigator of the finding by forwarding a completed copy of the "Incidental Finding Review Form" document (Appendix 8)
  - Clinical radiology reports of research scans conducted in the 3T MRI facility will NOT be issued unless they are requested via the procedure listed in **Section B** below.
  - Additional scans will not be performed by the MRI technologist to follow up on incidental findings.

b. Procedure for reporting incidental pathological findings: Principal Investigator Responsibilities

- If the MRI technologist detects an incidental finding, the principal investigator of the study will be notified. Alternatively, the investigator's research support staff may identify an incidental finding at a later time and notify the investigator of their finding.

- 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 MRI technologist to review the images and assist them in determining whether the subject should be notified of an incidental finding.

- Once the investigator 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.
  - Care should be taken to avoid unnecessarily alarming the individual, and terminology should be kept general and non-descriptive (i.e., "incidental finding" vs "lesion").
  - Keep in mind that we are not qualified to diagnose pathologies and cannot determine the significance of any abnormality detected.

- The investigator 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:
    - If the Principal Investigator is an **LHSC clinician:**
        - 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.
        - 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.

    - If the Principal Investigator is NOT an **LHSC clinician:**
        - 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.
        - The PI may provide them with a copy of their anatomical images on a CD/DVD to give to their physician, as well as a copy of the "Incidental Finding Review Form" (Appendix 8).
        - Family physicians and non-LHSC physicians can submit the images to LHSC radiology along with a request for a "*review of guest exam*".
        - 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.

- If the patient/volunteer does not have a family physician, the volunteer may be provided with a copy of their anatomical images on CD/DVD. 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*" (included in Appendix 8), and the report detailing the findings will be returned to the clinic.

- 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 paragraph "**If the Principal Investigator is NOT an LHSC clinician**" above may assist them in this process and help avoid unnecessary clinical MRI scans from being ordered.

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

- Investigators and TIRF 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 with the potential risk of discovering an incidental finding, they should not participate in the study.