

SOP Number :	220.02
Title :	Incidental Pathological Findings

Revision Chronology			
Version Number	Effective Date	Review Date	Reason for Change
220.01	August 3, 2021	January 21, 2022	Initial Version
220.02	January 24, 2022	January 10, 2023	Facility Name Change

 Director Signature

 Date

1. Scope

This SOP describes the procedure for reporting incidental pathological findings.

2. Procedures

The CenTRI facility staff are not trained, qualified to detect, or diagnose pathological findings. The facility does not have an in-house radiologist to routinely review images, and research radiographic imaging protocols generally do not include a full set of clinical images, which limits the ability to detect abnormalities. Therefore, the ability to detect incidental pathological findings are limited to the research protocol and to the training, experience of the CenTRI technologist, and study investigators. An incidental finding may be detected at the time of the scan or may be found by the investigator during image review. It is both the CenTRI 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 CenTRI technician confirms any abnormality during the scan:
 - Additional scan acquisitions should be avoided unless the CenTRI technologist deems it necessary to confirm or rule out the presence of an abnormality.
 - If an incidental finding is confirmed, the principal investigator of the study must be notified.
 - Additional scans will not be performed by the CenTRI technologist to follow up on incidental findings.

b. Procedure for Reporting Incidental Pathological Findings: Principal Investigator Responsibilities

- If the CenTRI technician 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.
- 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.