

SOP 18
Incidental Findings

MRI Facility

Centre for Neuroscience Studies

October 2020

Approved: October 14, 2020
Next Revision: October 2022

TABLE OF CONTENTS

1. Summary	Page 3
2. Facility Responsibilities	Page 4
3. Principal Investigator Responsibilities	Page 5
4. Appendix I – Incidental Finding Report	Page 6

SUMMARY

- i. The CNS MRI Facility is a research imaging center, and not a medical imaging center. The CNS 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 facility resources are available to peer-reviewed grant funded scientific collaborators with appropriate Review Ethics Board (REB) protocols in place. See SOP# 04 “New Protocols and Ethics Procedures”, and SOP #15 “MRI Facility Core Services”.
- ii. This document describes the procedures surrounding incidental findings discovered during human imaging studies at the CNS MRI Facility.
- iii. Incidental findings are defined as undiagnosed physiological abnormalities / medical conditions discovered by an MRI operator during a research-oriented scanning session. These findings are not typical to the research study in question at the time.
- iv. Most reviews (e.g. <https://onlinelibrary.wiley.com/doi/full/10.1002/jmri.25739>, and <https://www.bmj.com/content/363/bmj.k4577.full>), indicate approximately 1 - 2% of studies will contain incidental findings.

FACILITY RESPONSIBILITIES

- i. The MRI Manager, qualified MRI Technologists, and other trained operators are not diagnostic professionals and are therefore not qualified to identify all possible incidental findings. They are also not qualified to determine the severity or urgency of incidental findings.
- ii. A research imaging study will typically not acquire appropriate scans for the identification of many incidental findings, as may be requested in a clinical setting.
- iii. If an operator at the CNS MRI Facility discovers what they may believe to be an incidental finding, they will contact the MRI Manager immediately. The MRI Manager will confirm the incidental finding, and then contact (within 24 hours):
 - a. The Principal Investigator (PI).
 - b. A qualified radiologist if no previous arrangement was made by the PI to have a specific physician review their scans. The MRI Manager will provide the radiologist with a copy of any scans that identify the incidental finding so that they can be read properly. The MRI Manager will also provide basic demographic information (name, sex, date of birth, family physician).
- iv. Additional scans are generally not acquired, as the CNS MRI Facility staff are not trained medical professionals. A qualified radiologist will be responsible for determining if more imaging is necessary, and this will take place at a medical imaging center. The CNS MRI Facility does not facilitate additional scans on an exploratory basis.
- v. The CNS MRI Facility will work with the radiologist to ensure that the appropriate steps are taken to inform the participant's family physician and the participant if necessary.
- vi. The participant will generally not be informed on the day of the imaging session, as to not unduly alarm them before a proper assessment can take place. All operators will be trained to not alarm participants.
- vii. If the participant did not indicate, or does not have, a family physician, they will be provided with a copy of their images on CD. In this case, the radiologist will not be able to provide an official report but will provide recommended follow-up instructions. It is the responsibility of the PI to facilitate follow-up care (see the follow section: PRINCIPAL INVESTIGATOR RESPONSIBILITIES). In addition, the participant will be provided with a summary of the recommendation on a form with Queen's letterhead, which can be passed on to the clinic / following physician (see Appendix I). These can be taken to a walk-in clinic for proper follow-up care.
- viii. The CNS MRI Facility staff and operators are not trained to answer follow up questions regarding incidental findings.
- ix. Incidental findings are billed at a rate of \$200/finding, and this is billed to the research study / PI.

PRINCIPAL INVESTIGATOR RESPONSIBILITIES

- i. As stated above, the MRI Manager will quickly relay the discovery of any incidental findings to the Principal Investigator (PI).
- ii. Similarly, if the PI, or their research staff, discover an incidental finding that was missed by an operator of the CNS MRI Facility, they are to quickly inform the MRI Manager. The MRI Manager can then review the images, confirm the incidental finding, and advise as outlined above.
- iii. If the investigator expects their study to contain a significantly larger number of incidental findings than would be typically expected, they should make arrangements with a qualified radiologist to have these read. As stated above, it is not the responsibility of the CNS MRI Facility to make such arrangements. The MRI Manager may help facilitate these arrangements upon request (i.e., provide contact information). Any arrangements to have scans read should also be indicated in the informed consent for the participant.
- iv. The PI should indicate on their informed consent the following points related to incidental findings (pending approval and likely additions by Queen's University Research Ethics Board):
 - a. The definition, as outlined above.
 - b. That any incidental findings will be communicated to the participant in a timely and professional manner.
 - c. The CNS MRI Facility staff are not diagnostic professionals, these are not medical images, and we will not find, nor are responsible for finding, all undiagnosed medical conditions (see FACILITY RESPONSIBILITIES above).
 - d. The PI and CNS MRI Facility are not responsible for any costs that may be incurred as a result of the detection of an incidental finding and required follow up medical intervention. The participant agrees to the possibility of the discovery of incidental findings.
 - e. Any incidental finding discovered by our staff or the staff of the PI will be quickly read by a qualified radiologist, who will then attempt to contact the family physician indicated on the Safety Checklist for Research Subjects (see <http://neuroscience.queensu.ca/facilities/mri-facility#forms>) that every participant is required to complete before beginning a scanning session.
 - f. If the participant does not have a family physician, they will be provided with a copy of their images, an official letter, and instructions on follow-up care. The PI is responsible for facilitating this follow-up care.
- v. The PI should avoid publishing images containing incidental findings.

INCIDENTAL FINDING REPORT – CENTRE FOR NEUROSCIENCE MRI FACILITY

To whom it may concern,

During a voluntary research study at the Queen's University Centre for Neuroscience Studies MRI Facility, an incidental finding was discovered for the participant named below. These images were not medical in nature, however an operator at our facility discovered an abnormality that warranted medical professional consultation. A qualified radiologist reviewed the images and indicated that follow-up care is warranted. As the participant does not have a family physician, we provided them with a CD of their images and this letter. Please make arrangements for appropriate follow-up care. Do not hesitate to contact me if you require further information.

Thank you,
Donald Brien



MRI Manager
CNS MRI Facility
Email: briend@queensu.ca
Phone: 613-533-2811

Participant Name _____

Study Date _____

Reviewing Radiologist _____

AUTHORIZED SIGNATURES

Prepared by:

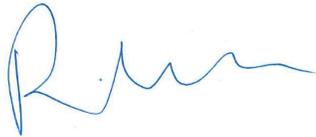


Donald Brien
Manager, CNS MRI Facility

October 14, 2020

Date

Approved by:



Roumen Milev, MD, PhD, FRCPsych, FRCPC
Director, Centre for Neuroscience Studies

October 14, 2020

Date