REB guideline for management of incidental findings in imaging studies

GUIDELINE STATEMENT

The use of imaging in research studies may generate **incidental findings** (see definition) that require a management strategy. Although each situation is unique, some general management strategies for Sunnybrook Health Sciences Centre (Sunnybrook) studies in which the Sunnybrook Research Ethics Board (REB) is the board of record are outlined below. Different hospitals may have alternate strategies for dealing with incidental findings which is relevant if Sunnybrook is not the board of record.

There may be legal implications of incidental findings that are identified on research scans. In particular, the presence of abnormalities on scans that if properly identified could have led to earlier intervention for various conditions should be considered. For example, the incidental finding of an early tumor on a scan that was not identified initially but found on retrospective review may be problematic.

Physicians engaged in research involving patients that undergo scans may be able to look to the Canadian Medical Protective Association (CMPA) for assistance. However, CMPA has previously advised physicians that control participants are not considered to be "patients" and therefore physicians engaged in research involving control participants cannot rely on CMPA for assistance. Sunnybrook has obtained insurance coverage through the Healthcare Insurance Reciprocal of Canada (HIROC) for the purpose of providing coverage to Sunnybrook and SRI staff (including physicians) for claims arising for bodily injury or property damage resulting from the conduct of studies involving humans including non-interventional imaging studies.

It would be best practice that a radiologist or a physician with relevant expertise reviews all imaging scans.

Article 3.4 in the Tri-Council Policy Statement (TCPS2) recognizes an obligation on the researcher to disclose incidental findings that have significant welfare implications for the participant ("**material incidental findings**") (see definition).

The TCPS2 also provides that a researcher may request an exception to the obligation to disclose incidental findings, based on impracticability or impossibility of disclosure to the participant. Such exceptions would be made by an REB on a case by case basis (Article 3.4).

DEFINITIONS

Incidental findings: unanticipated discoveries made in the course of research that are outside of the scope of the research (TCPS2).

Material incidental finding: an incidental finding may have welfare implications (i.e. be material) if the finding is reasonably believed to be accurately and reliably identified and either:

1) the finding indicates a potential health risk; OR
2) the finding is clinically actionable.

GUIDELINE

Here are some key considerations in developing an incidental findings management strategy, which should be part of the research protocol:

1. **Are the findings material?:** Determine if definitional criteria are likely to be identified in the proposed research.

2. **Exposure to risk:** If patients are exposed to risk in the research, they deserve a proportionally higher level of scrutiny. For example, due to associated risk involved with ionizing radiation, it is recommended that all scans are reviewed by a qualified interpreter.

3. **Qualified individual interpreting scan:** For all scans, it is recommended to develop a screening procedure to ensure a qualified individual has considered potential incidental findings. In some circumstances, it would be more appropriate to have a formal review of the scan by a radiologist or a physician with relevant expertise. It may be indicated to have a co-investigator join the study team for this purpose.

4. **Informed consent language:** It is recommended that informed consent language include an incidental findings management plan and description of potential implications and their significance. Additionally, the consent should clarify if the scan will be of diagnostic quality to avoid diagnostic misconception (similar to therapeutic misconception).

5. **Response to an abnormality:** If a suspected abnormality is identified appropriate follow up or consultation must be arranged by the investigators. Responsibility for making these arrangements should not be deferred to physicians outside the research project.

6. **Anticipate and prepare for common incidental findings:** Where common incidental findings are expected, prepare standard informed consent language. For example, incidental white matter hyperintensities are frequently seen in brain MRIs and should not elicit a diagnostic cascade and associated patient anxiety.

REFERENCES

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2018.

Revision History	
Version Date	**Summary of Changes**
April 18, 2022	Definitions: Minor modifications to section References: Addition of “References” section Revision History: Addition of “Revision History” section
August 1, 2017	Original version