Policy on incidental findings

Latest update: 2022-05-19

Approval by: Ives Levesque, PhD, FCCPM

This policy is effective as of: 2022-06-01

Context/background

MR imaging is a powerful diagnostic imaging modality when used by medical professionals with a diagnostic, clinical, or medical objective. In research, MR imaging can be used to answer specific questions about the human body for the goal of advancing science and human knowledge. During research studies, these magnetic resonance images may reveal abnormal or suspicious findings in research participants.

The management of incidental findings in Canada is informed by the *Tri-Council Policy Statement, Article 3.4*. This is summarized in the *Guidance in Applying TCPS 2 (2018) Article 3.4*, entitled "How to Address Material Incidental Findings"[1]. The responsibility for management rests with the investigator (or Study PI).

This policy defines how the MGH MRI Platform supports the application of the TCPS guidance applies to all users of the MGH MRI Research Platform and members of their associated research groups who work with any data collected at the MGH MRI Research Platform. The PI of the group is responsible for ensuring that research group members are familiar with this policy.

Definitions

An *incidental finding* is a "discovery about research participants or prospective participants that is made in the course of research but is outside the objectives of the research study"[2]. In this context, an incidental finding is any apparent atypical finding or abnormality noted on any series of magnetic resonance images from an examination conducted on a volunteer for research purposes, observed during a study, that may or may not have medical implications.

Material Incidental Finding: an incidental finding is *material* if it is "reasonably determined to have significant welfare implications for the participant or prospective participant." Only material incidental findings need be reported to participants. Material incidental findings *must* meet all 3 determinants defined in TCPS 2, which are briefly summarized below.

[1] https://ethics.gc.ca/eng/incidental_findings.html
[2] https://ethics.gc.ca/eng/incidental_findings.html#a3

1. Analytical validity: finding determined *not* to be an artifact of the methodology.
2. Potential significance: finding potentially important to disclose to the participant, as it may significantly affects the participant's welfare, or the welfare of the participant's close relationships (*e.g.* family), immediately or in a reasonably defined future,
3. Actionability: in sharing such findings in a timely manner, the participant can initiate an action to remove or help manage the risk to his/her welfare, and/or can use this information to take steps that may result in the research participant's benefit, or the benefit of their relatives.

For the purposes of this policy, the MRMD is designated the foremost expert in determining materiality, as they have the expertise and meet the standards of practice to make such determinations.

Notes:

There is normal variability in anatomical structure. Observers who are not trained healthcare professionals may observe imaging findings that appear to be abnormal. They should abstain from drawing conclusions based on such observations. Although incidental findings are rare, all such observations may be referred to this procedure.

In determining *materiality*, the Study PI may consult expert opinions. This policy sets forth the ways in which the MGH MRI Research Platform can support these efforts.

Scope of the policy

1. As indicated in the Terms of Use of the MGH MRI Platform, research exams conducted on volunteer participants cannot be considered as diagnostic and cannot be used as such by anyone including healthcare professionals.
2. MRI scans conducted for research at the MGH MRI Platform are not intended for diagnostic, clinical, or medical use. As such, they are not routinely reviewed by medical professionals for abnormalities. Should there be an incidental finding in the study, the researchers are responsible for ensuring it is addressed accordingly.
3. Researchers are not expected to ensure systematic review of images for incidental findings or any other medical abnormalities (beyond examination of images according to their research protocol).
4. Researchers are required by TCPS2 to address incidental findings regardless of the time at which the finding is observed, up to a reasonable period. For example, an incidental finding may be observed at a later stage, during image review or image analysis. It is recommended that the researcher meet this obligation until closure of the study.
5. Within the scope of guidance from TPCS 2, only *material* incidental findings should be reported to participants. Incidental findings are to be deemed as material on the basis of TCPS 2, as described above.
6. The MGH MRI facility commits to providing the services of experts to help determine the materiality of an incidental finding.

7. The MGH MRI Research Platform recommends that the Study PI (or delegate) inform research participants receiving an MRI scan of the possibility of incidental findings prior to participating in any research study.
8. The MGH MRI Research Platform recommends that research participants should not be shown any images collected during the imaging study.
9. As part of the consent process for participation in the study, research participants may be asked in advance of their participation for consent to review of the research images by a qualified health professional, if an incidental finding is observed.

Recommendation of consent and information

The MGH MRI Platform strongly recommends that a statement about incidental findings should be included on all consent forms for studies conducted at the MGH MRI Platform. Consent of the participant will be required for any assistance on incidental findings requested from the MGH MRI Research Platform. An example is provided below.

> *The MR imaging examination used in this study is designed to answer research questions. This procedure is not designed to examine your body medically. The images created during this procedure will not be reviewed by a health professional–unless explicitly required by the protocol for this specific study. This MRI procedure is not a substitute for one that a medical doctor would order, and it may not show problems that would be picked up by a medical MRI examination. In rare cases, the MR technologist or a member of the study team may notice unexpected abnormalities in a participant. In the unlikely event that an atypical finding is observed on the MR images of your body, images will be forwarded to a radiologist at the Montreal General Hospital for further review. If necessary, the radiologist will follow-up with you or your primary care physician. By signing this consent form, you agree to the release of the scan for review by a medical professional. It is possible that you could be unnecessarily worried if a problem were suspected, but not actually found. Material incidental findings are findings made in the course of the study that may have significant impacts on your current or future wellbeing or that of your family members. A material incidental finding concerning you in the course of this research will be communicated to you and to a health professional of your choice. At your request, the investigators can contact you or your primary care physician to help arrange medical follow-up to interpret the significance of the findings.*

Procedure

<u>Discovery and report of incidental finding</u>

1. If the MR operator or any other researcher observes a potential abnormality, the examination can be nonetheless completed. Interrupting the examination abruptly could prove to be unnecessary and cause undue stress to the participant. The participant will be thanked and compensated for their time according to study protocol.

2. The MR technologist or research team member who notices finding should report to the Study PI, independently of when the finding is observed. If the MR technologist or other Platform staff identifies the finding, they will report this directly to the Study PI. The rest of the procedure applies independently of when the finding is noticed.

Assessment

3. The Study PI may seek assistance from the MGH MRI Platform provided that they have obtained the consent of the research participant.
4. To obtain assistance in responding to an incidental finding and determination of materiality, the Study PI may report the finding to the MRMD by email* with exam date and a brief description of concern, under the Subject: "Incidental Finding – MGH MRI Platform", with copy to the Platform Manager.
5. Upon receipt of email, the MRMD initiates image review, to determine if the finding is *material*[3], by assessing:
6. Analytical validity
7. Potential significance
8. Actionability
9. The Platform Manager may assist the MRMD in retrieving the images for examination, either from the MRI system or with the help of the research group. The MRMD may consult with other healthcare professionals as needed and with Platform staff (*e.g.* Manager, Directors, MR physicist) on the potential for imaging artifacts.
10. The MRMD will produce a summary of the findings. This does not constitute an official radiology report.

* Email is not secure so participant identifiers should not be used (e.g., by name)

Reporting

11. The MRMD will follow up with the Study PI directly to report whether the funding is material or not. The Platform Manager may assist communication.
12. If the incidental finding is not material, the MRMD will provide the written summary of findings to the Study PI, and the procedure is complete. Non-material findings do not need to be reported to participants.
13. If the finding is deemed material, the MRMD will provide the written summary of findings to the Study PI, who will report the finding to the participant. In addition to the report, the MRMD can suggest an appropriate course of action that can be communicated to the participant.
14. While reporting, the MRMD may advise the Study PI with respect to the participant's inclusion in or exclusion from the study. It is the Study PI's responsibility to ensure that any impact on the participant's participation in the study, including withdrawal, is appropriately documented. The MGH MRI

[3] https://ethics.gc.ca/eng/incidental_findings.html#a5

Research Platform recommends that information about incidental findings be kept in writing by the Study PI in the study files.

15. Upon request in writing by the participant, the MRMD may contact the participant's physician and discuss the importance of the incidental finding. In such cases, the Study PI will provide the participant's contact information to the MRMD only. The Study PI may also provide the name and contact information of participant's primary care physician (e.g., family physician).
16. At their discretion and at the request of the participant, the MRMD may place a clinical requisition to conduct a clinical MR examination and/or refer the participant to a physician for medical follow-up.
17. Sharing of image data with the participant is governed by the MGH MRI Research Platform's policy. The comments from the MRMD can also be included with the images. These comments do not constitute an official report.

Confidentiality

All research data, including the possible significance of an incidental finding are covered by various statements of confidentiality. Once the MRMD (or the delegate) is contacted, the incidental finding becomes a healthcare matter and may be subject to various provincial and healthcare privacy policies.