Guidelines for Managing Incidental Findings in Research at CAMRI

Overview
When conducting MRI scans for research, it is possible that **unexpected incidental findings** may be seen on the images. These findings are unrelated to the original purpose of the research study but may still be of medical significance to participants. Typically, such findings are first identified by research staff or students who may **lack the clinical expertise** to determine their importance. As a result, it is essential to have a **clear, pre-approved process** in place for managing incidental findings ethically and responsibly.

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1. Planning for Incidental Findings: Ethics Application Requirements

As part of your **ethics application**, you must include a plan of how your study will handle incidental findings.

This includes:
- How incidental findings will be **detected**
- How they will be **verified**
- How and by whom they will be **communicated to participants**

Before your study can begin at CAMRI, you will need to provide your Ethics Committee Approval for:
- **The use of MRI within your research**
- Your **management plan** for handling incidental findings.

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2. Use of CAMRI's Incidental Findings Pathway, or developing your own one

You may **adopt CAMRI's existing pathway** for your study.
- CAMRI has developed an **Incidental Findings Pathway** for normal volunteers recruited for CAMRI teaching and MRI testing. This pathway is outlined in a flow chart at the end of this document. Please contact us if you require further information.

Alternatively, you may wish to adjust the standard pathway to be more appropriate for your own study.
- Studies involving participants with **known medical conditions** may yield a **higher rate of incidental findings**, which could require a tailored approach for review and disclosure. Some studies have very specific inclusion criteria. In these cases, you may wish to include a radiologist review of **all** the study images.

Any alternate management plan for incidental findings should maintain the same high ethical standards and be approved by your ethics committee.

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3. Radiologist Review of MRI

- If you do not have a radiologist, or other suitably qualified physician as part of the study team, CAMRI can assist with a **radiologist review** of the images.
- Be aware that **fees may apply** for any review or formal reporting of incidental findings.

- These costs should be anticipated and accounted for during **study planning and budgeting**.

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4. Understanding the Limits of Research Imaging

Radiology reporting of incidental findings is more limited than for clinical imaging:

- MRI images acquired for research purposes are tailored towards the specific research needs and are generally **not suitable for a radiological diagnosis to be made**.
- As a result, even when an incidental finding is identified it is **not appropriate to offer a diagnosis or differential diagnosis**.

Instead, after expert review, one of the following outcomes will be documented:

1. **"Yes, the participant should be informed and further investigated"**
2. **"No further action is required"**

Only once a review confirms that the finding may be clinically relevant, does the **potential** incidental finding become an **actual** incidental finding, and only then should the participant be informed.

⚠ CAMRI recommends that participants should not be informed based on **potential** incidental findings, **i.e. before confirmation by a radiologist.** Premature disclosure can cause unnecessary anxiety and confusion when findings later turn out to be false alarms or benign variants.

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5. Communicating Medically Significant Findings to Participants

- This disclosure should be made in a professional and compassionate manner, offering appropriate guidance for next steps.

- The **Principal Investigator (PI)** or another **senior member of the research team** will usually take responsibility for managing potential incidental findings, particularly those involving **normal (healthy) volunteers**.

- If the incidental findings are of medical significance, the research subject may be anxious and have concerns and questions, and the PI may wish to also include a registered medical practitioner to help disclose incidental findings to the participant.

- Where the research study team does not include any medical personnel, CAMRI may be able to help you find a medical practitioner to help with the disclosure. Please discuss these specific personnel needs with CAMRI in advance of submitting your ethics application, so these can be documented as part of incidental findings management plan within your Ethics Application.

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6. Participant Information Sheet (PIS): Suggested Language

- Informing research participants if incidental findings are confirmed, is the ethical and medically appropriate outcome.

⚠ CAMRI recommends that research subjects who **do not wish to be informed of incidental findings** are excluded from participating in the MRI research.

Your **Participant Information Sheet (PIS)** should include statements that clearly explain the issue of incidental findings.

These statements should ensure participants:

- Understand the limits of research imaging
- Know what to expect in the case of an incidental finding
- Are fully informed of the **potential implications**

The following statements are recommended:
“Because the images are not routinely reviewed by a radiologist, we are unable to perform diagnostic scans for medical purposes of areas where you have known abnormalities.”

“In the event that a condition assessed to be a clinical abnormality is detected during the research scan, you will be informed and advised to consult your general practitioner or another health professional of your choice.”

“If you do not wish to be advised of such findings, you will not be able to participate in this research project. We have adopted this position because it is not possible to make an informed decision to opt out of disclosure—given the wide range of possible findings and their unknown consequences.”

“Please note: once you have been informed that a clinical abnormality has been detected, this may impact your ability to obtain personal insurance, regardless of whether or not you pursue further medical evaluation.”

Summary Checklist for Researchers
Before beginning your study at CAMRI, ensure the following:

☑ Your ethics application includes a clearly described incidental findings process
☑ Your plan has been approved by the ethics committee
☑ You’ve budgeted for possible radiologist reviews
☑ You’ve budgeted for a possible registered medical practitioner for disclosures
☑ You’ve included appropriate wording in your Participant Information Sheet

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Revised June 2025

Incidental Findings Pathway