CAMRIS SOP #304
Incidental Findings in CAMRIS Research MRI Studies

Responsible Committee:	Effective From:	Last Approved:	Next Review:	Next Approval:
Safety	Feb 19, 2025	Feb 19, 2025	Dec 1, 2025	Feb 1, 2026

1. Purpose

This standard operating procedure (SOP) describes the process for handling incidental findings in research MRI studies carried out under the auspices of CAMRIS.

CAMRIS considers incidental findings as part of protocol review, makes recommendations regarding the evaluation of research MRI studies for incidental findings, and in some instances assists in the interpretation and management of incidental findings.

Incidental findings are unexpected abnormalities or lesions that are discovered during the acquisition or analysis of MRI data. They are unrelated to the purpose of the research study and may or may not be clinically significant. Incidental findings are considered a risk of participating in research MRI studies because they can cause anxiety or suggest the need for additional medical evaluation that may carry risk or costs but, in some cases, participants may also benefit from the early discovery of an addressable abnormality.

The likelihood and incidence of incidental findings depends on the study population, the MRI scanning protocol, and the extent of formal review. While incidental findings are common particularly when research MRI scans are formally reviewed by a radiologist, significant incidental findings requiring further evaluation and/or management are rare.

2. Scope

This process applies to research MRI data acquired on MRI systems operated by CAMRIS. This includes research-dedicated scanners, and research-shared scanners when being operated by CAMRIS for research imaging.

3. Instructions and Procedures

3.1. Incidental findings considerations in the CAMRIS application review process

The CAMRIS application review includes an assessment of the likelihood of significant and actionable incidental findings to ensure that appropriate evaluation for incidental findings is planned. This determination is made based on information provided in the application and the clinical expertise of the CAMRIS committee. Based on this determination, one of several approaches are considered appropriate:

3.1.1. *Studies in clinical populations with a potentially high likelihood of incidental findings*. If the CAMRIS committee determines that the study population has a high likelihood of actionable incidental findings, a formal radiological review of structural MRI data is stipulated as a condition of protocol approval. There are several mechanisms for this, described in 3.3 below. Even if a

clinical research study includes central review of MRI, local review may be stipulated if the committee has concerns about the potential for abnormalities requiring immediate action.

3.1.2. *Studies in clinical populations with known structural MRI abnormalities*. Some clinical populations have chronic disorders associated with known structural MRI abnormalities. For such studies, if the risk of an actionable new incidental finding is deemed to be comparable to that of a healthy participant, the CAMRIS committee may determine that formal radiological review is not needed.

3.1.3. *Studies in healthy populations*. Research MRI is also frequently carried out in healthy participants. These populations are generally considered to have a low risk of actionable incidental findings, and formal radiological review of MRI data is typically not required.

3.2. Required clauses in IRB protocols and consent forms related to incidental findings

As part of the CAMRIS application review, compliance with the following regulatory requirements is evaluated:

3.2.1. Because incidental findings are considered a risk of participation in research MRI, IRB protocols and consent forms must disclose the risk of incidental findings. CAMRIS provides standardized verbiage for this on our website, but for studies carried out under a central IRB analogous verbiage is acceptable.

3.2.2. Because some research participants may volunteer for research MRI studies believing that the study will also screen for clinical abnormalities, in most cases the consent form must also inform participants that research MRI studies are not intended for diagnostic purposes. CAMRIS provides standardized verbiage for this on our website, but for studies carried out under a central IRB analogous verbiage is acceptable.

3.3. Mechanisms for incidental finding review

There are several processes for incidental finding review that can be specified in the CAMRIS application and/or stipulated by the CAMRIS committee, including:

3.3.1. Research Report (RESREPORT). Clinical MRI services offers radiological review of structural data included in some research MRI studies ordered in PennChart. A per-study fee is charged to the user (current rates are posted on the rate sheet on the CAMRIS website).

3.3.2. Research Read (RES). Research MRI studies can include a radiologist on their study team who agrees to perform review of all scans ordered in PennChart, which can include review for incidental findings. In these cases, the research MRI data is directed to that radiologist's clinical MRI interpretation queue.

3.3.3. Non-PennChart review. For studies in populations with known chronic disorders with associated MRI findings and a low risk of actionable incidental findings, a clinician member of the investigative team (often the principal investigator) assumes responsibility for reviewing the MRI data for incidental findings. These studies are not required to be ordered in PennChart.

3.3.4. No review. In some studies, the risk of incidental findings is low, and no formal or informal review is stipulated. This typically applies to young and/or healthy participants but may occur in other populations.

Regardless of the formal process used for review of a particular protocol, incidental findings may also be noted by the research MRI technologists or other research personnel handling the MRI data.

3.4. Management of incidental findings

Key aspects of incidental finding management are described below.

3.4.1. Incidental findings must be assessed for their clinical significance with regard to the need for further medical evaluation or management and the need for disclosure of the finding to the research participant. For study teams that include a radiologist or those using RESREPORT, the radiologist screening for incidental findings will perform this assessment. When a radiologist is not involved in the screening, the incidental finding should be reviewed by a member of the CAMRIS committee with relevant radiological expertise.

3.4.2. Incidental findings requiring further medical evaluation or management must be disclosed to the research participant. Some incidental findings that are not actionable should still be disclosed to the research participant. This applies to most benign lesions that would be reported as abnormalities in a clinical MRI study or would preclude effective use of the subject's data in research studies.

3.4.3. The handling of research risks such as incidental findings, including disclosure to the participant, is the responsibility of the study's Principal Investigator. For some studies this responsibility is delegated to a clinician co-investigator. It is the study team's responsibility to notify the Principal Investigator if an incidental finding is suspected.

3.4.4. Where incidental findings occur in a healthy volunteer protocol without a clinician co-investigator, clinicians in the CAMRIS committee with relevant expertise may assist. Study Principal Investigators can request this assistance from the CAMRIS committee member who communicates the assessment of the incidental finding.

Date:	**Description of Revision**
Feb 19, 2025	Initial version