SOP Number **OCMR_006**

SOP Title **Dealing with non – cardiac incidental MRI scan findings**

	NAME	TITLE	SIGNATURE	DATE
Author	Dr Oliver Rider	Deputy Clinical Director	O. Rider	02/09/2016
Reviewer	Jane Francis	Head of Imaging Applications	J. Francis	01/09/2016
Reviewer	Dr Hanan Lamlum	Head of Clinical Research Coordination	H. Lamlum	27/09/2016
Authoriser	Prof Stefan Neubauer	Clinical Director	S. Neubauer	06/09/2016

Effective Date:	September 2016
Review Date:	September 2018

1. PURPOSE

Occasionally in the course of scanning an otherwise unknown abnormal anatomy or pathology is detected. This is known as an incidental finding. The purpose of this standard operating procedure (SOP) is to describe the way that OCMR will provide a commitment to report such findings so that the participant or volunteer's interests are best served.

2. SCOPE

This SOP relates to all research **non-cardiac** MRI scans performed on humans in OCMR. Research cardiac MRI scans are subject to a separate procedure outlined in SOP OCMR_005.

3. INTRODUCTION

This document describes the procedures that should be followed when an incidental finding is detected on a non-cardiac MRI scan in OCMR. This SOP covers all non-cardiac research scans.

It should be noted that dealing with abnormal scans is an extremely sensitive issue and needs to be dealt with in a very careful and methodical way. It is important that the relevant research participant **should not be unduly alarmed by the finding**. In the event that an incidental finding is noted the investigator or scan operator **should not attempt to discuss the finding with the participant during their scanning visit**. If an abnormality is noted when the participant is still in the magnet, the acquisition of additional scans should not be performed. All actions should also be in keeping with the reporting of incidental findings as specified in the study specific protocol.

4. RESPONSIBILITIES

Scanner Operator or Research Fellow

Having noted an incidental finding, the scanner operator should not comment on what they believe the incidental finding might be. They should initially contact the Head of Imaging Applications (or nominated deputy).

Head of Imaging Applications

The Head of Imaging Applications (or nominated deputy) should review the scan from a technical perspective. The researcher is responsible for informing the Principal Investigator (PI) if an incidental finding is suspected.

Principal Investigator (PI)

It is the responsibility of the PI to provide specific plans for dealing with incidental findings and to supply these details to the Head of Imaging Applications prior to a study being authorised at OCMR. Individual research protocols should contain specific plans for the contingency of incidental findings.

The PI must supply the name and contact details of a nominated radiologist who is able to give a radiological opinion on the incidental finding.

The PI must provide the details of a clinician who is able to pursue an incidental finding if necessary.

The PI is responsible for recording the incidental finding in the case report form (CRF)

All PI's will be responsible for ensuring that this information is provided to OCMR prior to any study being authorised.

5. SPECIFIC PROCEDURES

An incidental finding may be detected either at the time the scan is acquired or may be identified some time later, potentially months or even years after the scan was acquired. Regardless of the time elapsed, as soon as any abnormality is detected the following course of action should be followed:

Any scan that raises cause for concern should, in the first instance, be shown to the Head of Imaging Applications or a nominated deputy as soon as practically possible, to exclude a technical / acquisition cause. A note should be made in the case report form (CRF) to document the date the finding was identified and the date of demonstration to the Head of Imaging Applications (or nominated deputy).

The Head of Imaging Applications will make an initial decision as to whether the incidental finding is potentially an abnormal anatomy / pathology. If the Head of Imaging Applications determines the incidental finding to be non-significant at this stage then no further action will be taken.

In the event that the Head of Imaging Applications determines that the scan warrants further inspection the PI for the study must be informed as soon as possible. It is then the PI's responsibility to ensure that the nominated radiologist and clinician are informed and the incidental findings are reviewed. If the resulting decision is that the finding requires further investigation it is the responsibility of the PI to ensure that the participant is informed and is invited to discuss the finding with the clinician. It is the responsibility of the clinician and the PI to ensure that further investigations or referrals are arranged as appropriate (with the participant's permission).

6. NOTES ON PARTICIPANTS VIEWING SCANS

A volunteer or research participant should not be confronted with an abnormal scan finding during their scanning visit. Participants should not be shown the images from their scan during their visit. Promises to show participant their scan should be avoided both during recruitment and during the scan session itself.

Participants should not be provided with images from their scans to take away, this invites the temptation for participants to attempt to interpret their scans when they are not trained to do so. If images are provided the following text should be appended to the bottom of the images:

"These images are for research purposes only and are not intended for diagnostic use"

5. INTERNAL AND EXTERNAL REFERENCES

For cardiac incidental findings see OCMR SOP_005 (https://www.ocmr.ox.ac.uk/documents)

6. CHANGE HISTORY

SOP no.	Effective Date	Significant Changes	Previous SOP no.
OCMR_006	September 2016	New Version	Neuro_002_V2