



SOP Number OCMR_005
 SOP Title Dealing with cardiac incidental MRI scan findings

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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 only to research cardiac MRI scans performed on humans in OCMR. Clinical cardiac scans are **NOT** included in this SOP as incidental findings would be included in the clinical report. Incidental findings for non-cardiac studies are subject to a separate procedure outlined in SOP OCMR_006.

3. INTRODUCTION

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

It should be noted that dealing with abnormal scans is an extremely sensitive issue which needs to be dealt with in a very careful, methodical and timely manner. 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 until a CMR consultant has formed an opinion of the finding**. 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, Research Fellow or Radiographer

Having noted an incidental finding, the scanner operator 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 and should also refer it to a CMR Consultant as soon as practicable.

CMR Consultant

The CMR Consultant should form an opinion of the scan and decide whether the abnormal finding requires further action.

The Principal Investigator (PI) should be informed if further action is needed. The CMR consultant should then oversee arrangements to contact the participant and to ensure that the participant's GP is notified (if the participant gives permission).

5. SPECIFIC PROCEDURES

An incidental finding may be detected either at the time the scan is acquired or 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 file (CRF) to document the date of noticing the finding and the date of demonstration to the Head of Imaging Applications.

The scanner operator or research fellow who obtained the images should then present the finding in the usual manner at the weekly case reading session, where at least one CMR consultant will always be present. The CMR consultant will then decide whether the incidental finding needs to be pursued. It should be stressed that the participant concerned should **NOT** be contacted at this point and that the number of people involved in the overall process should be kept to a minimum.

If the CMR consultant determines that the finding does not need further investigation the case will be closed and no further action taken.

If the incidental finding is determined to warrant further clinical investigation then the clinical research fellow should follow the procedure as outlined in this SOP and the study specific documents.

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 are not to be shown the images from their scan during their visit. Promises to show a 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. In the unlikely event that 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"

7. INTERNAL AND EXTERNAL REFERENCES

For non-cardiac incidental findings see OCMR SOP_006
(<https://www.ocmr.ox.ac.uk/documents>)

8. CHANGE HISTORY

SOP no.	Effective Date	Significant Changes	Previous SOP no.
OCMR_005	September 2016	New Version	OCMR Cardiac_001