

# Manchester Metropolitan University Standard Operating Procedure: Management of Incidental Findings identified by Magnetic Resonance Imaging (MRI)

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## 1 Introduction

This Standard Operating Procedure (SOP) describes the process that Manchester Metropolitan University staff and students must follow in the event of any incidental finding being observed during the use of the University Magnetic Resonance Imaging (MRI) scanner. This SOP covers all individuals scanned by the University MRI scanner including research participants and scanning individuals for any other purpose.

## 2 Background

Incidental findings are defined as observations of potential clinical significance unexpectedly discovered during a non-diagnostic process, unrelated to the purpose for which an individual is being scanned. In the Manchester Metropolitan University context, the MRI scanner is used for research and legitimate University purposes and is not currently used for diagnostic purposes. However, even though this is clear to scanned individuals; researchers, specialist technical staff and other University authorised operators have a duty of care to follow up any incidental finding that it is identified during the procedure.

## 3 Purpose

This Standard Operating Procedure (SOP) establishes the procedure Manchester Metropolitan University researchers, specialist technical staff and other University authorised operators should follow upon the identification of an incidental finding when using the MRI scanner.

## 4 Procedure

### 4.1 Imaging Incidental Reporting plan

#### *Study procedures for the reporting of incidental findings*

A description of how incidental findings will be managed and reported must be detailed in the protocol, the likelihood of incidental findings and reporting mechanisms should also be specified. The information must also be clear in the application for ethical approval.

#### *Participant information sheet*

The Participant Information Sheet (PIS) must also explain incidental findings, what they are and what will happen if an incidental finding is identified. Please see Appendix 1 for the template wording.

#### *Consent form*

The consent form must include a statement giving consent for the Radiologist and GP to be informed upon the identification of an incidental finding. The template wording can be found in appendix 2.

#### *Medical history template*

A medical history template must be prepared and submitted along with the application for ethical approval. This should ask information about any medical history that may contraindicate the use of the MRI scanner and, any other information such as previous surgery, gender, age, and any medical history relevant to the MRI scan being taken.

If you have any questions about this, please contact James McStravick ([james.mcstravick@mmu.ac.uk](mailto:james.mcstravick@mmu.ac.uk)).

#### *Notifying the person scanned.*

The protocol, application for ethical approval and associated participant facing documents e.g. participant information sheet and consent form, should be clear on the incidental findings process that will be followed. A document where GP details can be collected along with a GP letter template must also be prepared and submitted along with the application for ethical approval.

### **4.2 Notifying the Radiologist of a new research project**

Once all approvals for research involving the MRI scanner are in place, the radiologist will need to be informed that the research is starting and the planned duration of the project by the Manchester Metropolitan Radiographer. The associated contact details can be found in appendix 3.

Once notified, the radiologist will inform the radiographer of any periods of planned leave.

### **4.3 Notifying the Radiologist of a potential incidental finding**

#### *I. Procedure for notification*

Where a potential incidental finding has been identified by the radiographer, the radiologist must be contacted via email (contact details can be found in Appendix 3) and sent the scan via the University approved archiving system, Azure\*, for review. Along with the scan, the medical history form, and contact details of who the scan should be sent to must also be included.

Where an urgent review is needed, the radiologist must be contacted via telephone (Appendix 3) before the scan is sent via Azure.

Where an incidental finding has been confirmed, the participants GP must be notified by the Manchester Metropolitan Radiographer as per the procedure set out in the application for ethical approval and protocol. The research team must also notify the person scanned of the GP notification. A script of what will be said will be said / sent to the GP and person scanned must be included in the application for ethical approval.

#### *II. Review timeframes*

**Standard review:** Once received by the radiologist, the standard timeframe for review of the scan will be 7 days.

**Urgent review:** Once received by the radiologist, an urgent review (as defined by the Manchester Metropolitan Radiographer) will be completed in 48 hours.

These timeframes will vary during periods of leave and any change in these will be notified when the radiologist is informed of a new project (section 4.2).

### **4.4 Radiologist invoicing**

The radiologist review fee is £250. Invoices must be sent to the S&E RKE team ([SciEngRKE@mmu.ac.uk](mailto:SciEngRKE@mmu.ac.uk)) where payment will be arranged.

## **5 Related Documents**

**Appendix 1:** Incidental finding wording for the participant Information sheet.

**Appendix 2:** Wording for consent form.

**Appendix 3:** Radiologist contact details.

\*Azure will not be available until August 2022. If any incidental findings are identified before it is available, Dropbox Business can be used.

## Appendix 1: Incidental finding wording for the participant Information sheet.

### ***Incidental findings***

*The MRI scan we will be taking as part of this research / project [please choose one] is not intended for diagnostic purposes, only for the purpose of this research / project [please choose one]. There may be some occasions where the research team will see something on a scan that is unexpected and could be a previously unidentified medical problem. This is also referred to as an incidental finding.*

*If an incidental finding is identified in your scan, with your agreement your scan will be sent onto a radiologist (acting as our processor), who will look at your scan to determine whether any further follow-up is needed. The scan and the medical history form you completed before being scanned will be sent also. We will ensure all your personal data is transmitted securely and will take steps to help ensure that only designated individuals are able to access your data.*

*If the radiologist thinks the finding needs to be investigated further, the research team will contact your GP with a description of the findings and a copy of the scan so this can be arranged. We will also notify you directly of any incidental findings using the contact details you provide, and will advise you to make an appointment with your GP in these instances so this can be discussed further.*

*Our lawful basis for processing your personal data and sensitive special category personal data in this way is public task, and for the purposes of medical diagnosis. We will retain details of such findings, including a copy of any referral we make for a period of [insert retention period as per University policy] years.*

*If you have any questions about this, please speak to your research team.*

## Appendix 2: Wording for consent form

The below wording should be inserted into your consent form as a separate statement for all research / projects involving Manchester Metropolitan University's MRI scanner.

*I understand that it is possible that an MRI scan may reveal a pre-existing medical problem which I was not aware of. If this occurs, I give researchers permission to contact the radiologist linked to the University and, if needed, my GP.*

### Appendix 3: Radiologist contact details.

Teik Chooi Oh

Chosen Link Ltd

Email: [chooi@doctors.org.uk](mailto:chooi@doctors.org.uk)

Mobile: 07745978000