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<h1>Incidental Findings</h1>	
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Author: Nooreen Shaikh, Ethics and Research Governance Coordinator	
Approved by: Ruth Nicholson Head of Research Governance and Integrity	Date:

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## 1. PURPOSE

This standard operating procedure (SOP) describes the steps that should be taken in the event of any incidental finding being observed during the conduct of a research study. This SOP does not cover findings that fall under standard clinical care. This SOP can apply to all research participants, including healthy volunteer research participants.

## 2. INTRODUCTION

Incidental findings are defined as observations of potential clinical significance unexpectedly discovered in research participants and unrelated to the purpose of the study. These may include for example abnormal or unexpected findings from laboratory samples or from radiology images. The primary purpose of research is to answer a research question, however as a result of additional tests that are undertaken as part of a research study incidental findings may become apparent. Therefore, the researchers have a duty of care to follow up on any incidental findings that are identified as part of a research study.

## 3. RESPONSIBILITIES

### 3.1. Chief investigator

- To ensure that the likelihood of incidental findings are considered.
- To consider reporting mechanisms for the receiving, and dissemination of incidental findings, including for healthy volunteers and for research undertaken outside of the NHS.
- To include the above in the ethics application, protocol, participant information sheet and GP letter as required.
- To ensure that principal investigators (PI) are aware of the reviewing and reporting requirements.

### 3.2. Principal investigators

- To ensure incidental findings are reviewed and managed appropriately including review by other clinicians as required.
- To ensure findings are communicated to GPs or other clinicians as appropriate.
- To ensure findings are communicated to the participant.
- To ensure all team members are suitably trained with respect to management of incidental findings.

### 3.3. All research staff

- To ensure they report any suspected incidental findings to the PI.

## 4. PROCEDURE

## 4.1 Study Set Up

During the set up of the study, a description of how incidental findings will be managed and reported should be detailed in the protocol, the likelihood of incidental findings and reporting mechanisms should also be included in any ethics application form as required. The protocol should state if incidental findings will require feedback to the clinical care team or participants' GP, as well as them being reported to the participants themselves. For healthy volunteer studies, the best reporting route should be considered and this should also be documented in the ethics application form. It should be considered during set up whether or not incidental findings will be sent to the research participant, and the decision on this should be ethically approved. For instance, potential benefits and harm of feedback should be assessed.

The participant information sheet should also explain to the participant the reporting procedure if any incidental findings do occur.

If the participant's GP is to be informed, then the appropriate clause should be added to the consent form.

## 4.2 During the Study

If an incidental finding is observed during a procedure which is carried out as part of the research protocol, and it is considered a significant abnormality, then the study team should report these to the PI who should take action accordingly, taking into account the procedure described in the protocol and participant information sheet.

If incidental findings do become apparent, then a decision should be made and documented if the participant is able to continue in the research project (depending on their length of time in the project).

Appropriate checks should be made during the study to ensure that any incidental findings are reported as per the protocol.

## 5. REFERENCES

**ICH Guideline for Good Clinical Practice E6 R2**

**[Management of Incidental Findings Detected During Research Imaging](#)**, Royal College of Radiologists 2011

[Framework on the feedback of health-related findings in research](#)