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Incidental Findings	
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Version	**Date**	**Reason for Change**
Version 1.0	24 Jan 2020	NA
Version 2.0	19 Oct 2020	Scheduled Review Templates removed and administrative changes to SOP. JRCO name change to RGIT
Version 3.0	09/ Jan / 2024	Scheduled Review

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PURPOSE

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

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.

Discovery of these extras can result from a standard, approved clinical test or intervention. They can also be found from a research test or intervention. Each incidental finding has an impact on how you may need to handle the result and what happens with that result.

In some studies, it may be impossible to provide incidental findings because the subjects are de-identified or anonymous, for example, certain tissue banking activities, research conducted under a waiver of consent, exempt studies, and cluster randomised studies.

Incidental findings in research are becoming increasingly common due to the advances in imaging and genetics research. Investigators must consider the possibility of IFs as part of the assessment of the risks and benefits of research participation and must have a plan for reporting results.

Examples of an Incidental Findings

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1. A possible brain tumour or a vascular malformation found on a functional MRI scan.
2. A laboratory test abnormality found as part of screening for a clinical trial or for baseline physiologic data on a "healthy" control subject.
3. A possible genetic abnormality or risk factor.

RESPONSIBILITIES

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.

Principal investigators

- To ensure incidental findings are reviewed and managed appropriately including review by other clinicians (clinical care team) 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.

All research staff

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

PROCEDURE

4.1 Study Set Up

If you are conducting research that has a potential to uncover an incidental finding, it is best to plan ahead for how you'll treat the result and if you plan to return that result to a participant.

While most participants desire to have their results returned, there are circumstances where it might not be in the participant's best interest to receive a result.

It is important to consider the design of the research, as well as the interventions proposed, in order to formulate a plan for if and when any incidental findings should be returned to individual participants.

For example, is the intervention done for research purposes, standard care, or both? If the intervention is done for research as well as for standard clinical care, and the interpretation of the results would occur anyway, the results should be disclosed to the participant and/or the participant's physician.

However, if the research intervention is not approved for use clinically, generally, the findings should not be disclosed to the participant. This information should clearly be outlined in the informed consent form (ICF) and protocol.

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.

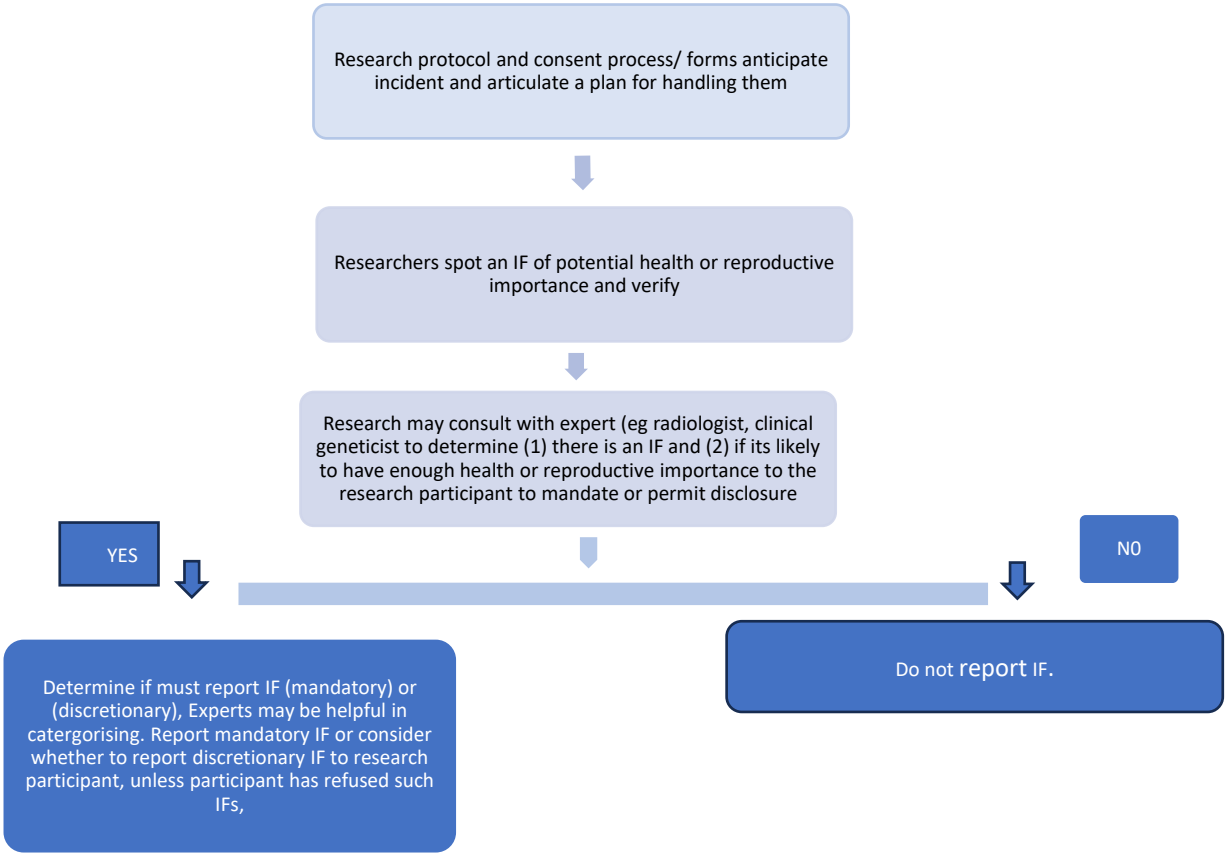
4.2 During the Study

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.

RECOMMENDED PATHWAY FOR HANDLING IFS IN RESEARCH



5 REFERENCES

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Management of Incidental Findings Detected During Research Imaging. Royal College of Radiologists 2011. Cited 01/12/2023

Framework on the feedback of health-related findings in research. Cited 01/12/2023

What do I do About Incidental Findings in Research? (advarra.com). Cited 01/12/2023