Guide to reporting incidental findings

Victorian Biomedical Imaging Capability (VBIC)

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1 Disclaimer

The information contained in this document is a guide only and no VBIC or non-VBIC site is compelled to implement this guide. The VBIC Coordination Committee takes no responsibility for the success, failure, competence or capability resulting from the implementation of suggestions made in this document. All imaging facilities and imaging researchers should review this information in the context of their own ethics applications (and approvals), quality control, quality assurance, training and risk management strategies. Those seeking to implement this guide are advised to check it against their specific ethics approval(s) and their organisation's legal and insurance regulations.

2 Definitions

Incidental finding	An incidental finding amounts to the identification of an abnormality from the subject's scan. However, this finding is not the purpose of the scan or a part of the research purpose or intent
Researcher	The person (medical doctor, imaging physicist or other person) leading the research
Subject	Person volunteering to have one or more MRIs of their brain for the purposes of research
Adverse finding	An incidental finding that has clear negative consequences for the subject
Participant	See Subject

3 The aim of this document

The purpose of this document is to discuss the ways incidental findings can be handled and their pros and cons. This discussion is based on a review of relevant node documents and input from Node Directors. The outcome of this document is to guide researchers and radiologists in the management of incidental findings in a range of studies (but primarily brain-based MRI scans).

4 What is an incidental finding and what does it mean to find one?

An incidental finding is an abnormality discovered unexpectedly in research subject during medical research. A clinically significant incidental finding is one that indicates a subject's present or future state of health is likely to be affected by the finding. These findings could range from an aggressive tumour to a structural variance of no significance to an observation implying a slightly increased risk of degenerative condition 50 years into the future.

5 What are the obligations of the centre in the case of an incidental finding?

Centres do not have an obligation to report or not report incidental findings. For most (if not all) imaging research the relationship is between the researcher and the subject. The centre should work with the recruiter to ensure the promises made to the subject about identifying, analysing and reporting incidental findings can be achieved (see sections below).

However, it is our collective view that centres must have a stated position on the reporting of incidental findings. This position should cover whether or not it can/will or can/will not report incidental findings, how these findings can/will be managed and/or reported. This information should be made clear to the researchers using the centre's equipment and appropriately included in ethics applications (and therefore patient consent forms).

6 What are the obligations of the researcher in the case of an incidental finding?

Researchers must be aware of the capabilities of the imaging centre they are using. The must work with the centre to create the relevant ethics application(s) and associated patient consent forms that reflect their position on the reporting of incidental findings. In making such a decision, the research should consider that incidental findings are common. A recent study by the Florey Institute of Neuroscience and Mental Health[1] showed 13% (66 of 491) of subjects had an incidental finding reported by a radiologist (across a range of studies conducted at their site). Of those, 38% (25 of 66) were deemed to require a follow-up scan after neurological review and 72% (18 of 25) of those were deemed *priority* follow-up cases. Of course, that means 62% (41 of 66) had nothing to worry about. Thus, the health risk posed by the incidental finding might be less significant than the anxiety their disclosure could generate (e.g. subject anatomy differs from the text book norm; non-functional findings).

It could be argued that incidental findings with serious health implications should be reported to the subject on ethical grounds – regardless of the subject's desires regarding being informed – given the health implications.

Ultimately a researcher could adopt one or more of the following positions:

1. Report 100% of incidental findings, regardless of subject preference
2. Report 0% of incidental findings, regardless of subject preference
3. Report findings only based on subject preference
4. Report findings with health implications, regardless of subject preference
5. Report findings with health implications, based on subject preference

With their position in mind and working within the capacity of the centre, the researcher should create a consent form that aligns with their stance on reporting incidental findings. The form should clearly state what findings will be reported (e.g. all incidental findings, no incidental findings, opt in or opt out) and if selecting a certain option will exclude a subject from a study (i.e. some sites include a question "*would you like to be notified about adverse findings*" and if the answer selected is "*no*" subjects are informed they cannot participate in the research).

Finally, some researchers take the stance that, it is better to educate the subject about symptoms that might be considered warning or trouble signs, and advise her/him to return only if such symptoms develop, rather than report on incidental findings.

Why:

- **Not report an incidental finding:** by not reporting, it could save a lot of resources such as money (cost of acquiring radiologists and medical practitioners to confirm incidental finding; costs of follow up scans) and time. Furthermore, some centres and research projects are not equipped (funded) to perform the work that is required in the case of an incidental finding. It could also prevent psychological and financial burden for the subject.

- **Report an incidental finding:** the subject could have a serious condition that might impact the quality of his/her life. By reporting the finding, treatment can be arranged that could potentially save a life. With this comes reputational benefits for your facility and also the added benefit of being associated with alert, morally aligned staff.

7 Procedures for reporting incidental findings

In order to identify and report incidental findings, researchers (and centres) should develop a patient (subject) consent form. They should also document their specific process for reporting incidental findings.

[1] Ansari, S., Farquharson, S. Speare, S., Mandelstam, S., Jackson, G. &Connelly, A. (2012). Incidental findings in neuro-imaging research: The impact of neurological opinion on the need for clinical follow up. *Brain Research institute, Florey Neuroscience Institutes*

7.1 Patient (subject) consent form

As part of the consent form and in the context of the researcher's stance on incidental findings, the patient should be able to advise:

1. What kind of findings they would like to be notified about (if any) e.g. all incidental findings or just those of medical/health relevance.
2. The doctor of choice or radiologist that they would like to talk to in the event of an adverse finding (particularly relevant for studies where subjects have been recruited through doctors or other medically qualified practitioners.

It should also be clear to the subject that there are:

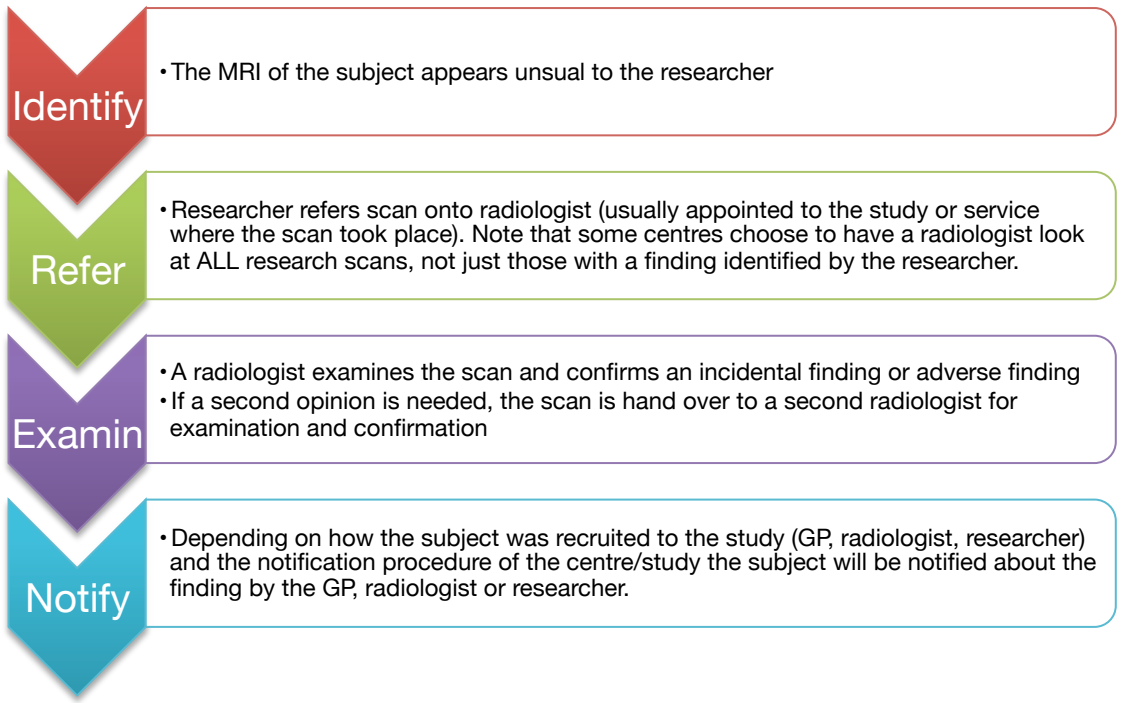
1. Insurance implications, where patients have a duty to disclose their knowledge of a problem to the relevant life or other insurer.
2. Costs (for further actions/follow ups, etc.) that will not be borne by the research study and will (usually) be borne by the subject in a non-research facility.

7.2 What happens in the case of an incidental finding?

1. MRI scan of subject appears unusual to the researcher
2. Researcher refers scan onto radiologist (usually appointed to the study or service where the scan took place). Note that some centres choose to have a radiologist look at ALL research scans, not just those with a finding identified by the researcher.
3. A radiologist examines the scan and confirms an incidental finding or adverse finding
4. If a second opinion is needed, the scan is hand over to a second radiologist for examination and confirmation
5. Depending on how the subject was recruited to the study (GP, radiologist, researcher) and the notification procedure of the centre/study the subject will be notified about the finding by the GP, radiologist or researcher.

This is visually presented in Figure 1.

Figure 1: Schematic of identification leading to notification (reporting) of an incidental finding



7.3 What findings should be discussed with the subject?

Each centre will need to determine what findings (if any) it will discuss with the subject. As noted above, depending on the researcher's reporting decisions, the subject can make the choice of whether or not they wish to be informed about all incidental findings or only those adverse findings that need immediate action. This could be any abnormality, only abnormalities with health implications or only abnormalities with urgent health implications.

As we noted earlier, if all incidental findings are reported to the subject it will increase the costs and time of the research for limited to no benefit for all parties involved.

However, if a researcher does not report any incidental finding the subject's life may be at risk in the near future and an opportunity to save a life or influence someone's quality of life is missed. This may present an ethical issue for some researchers and centres. Therefore, centres and researchers need to work together to ensure their ethics are aligned and adopt a policy that excludes all subjects who do not wish to be informed about any incidental findings.

What are the insurance implications of incidental findings?

Presuming centres and researchers are appropriately insured, there are no additional insurance implications for the centre or the researcher related to incidental findings.

However, there are implications for research subjects. In particular, health and life insurance policies require policy holders to disclose relevant information the holder is aware of. Being aware of an incidental finding may necessitate the subject make a disclosure to their insurance company(s). This may lead to premium increases, refusal of coverage or cancellation of the entire policy.

What are the costs of following-up on incidental findings and who is responsible for these costs?

Any incidental finding will require further examination (by trained professionals or further tests) to confirm the nature of the finding (essentially the level of health risk faced by the subject). These costs are usually borne by the researcher/research project prior to disclosure to the subject.

Once the subject has been notified of an incidental finding, (for the most part), further examination or testing costs are borne by the subject. Thus, the potential for costs arising from incidental findings should be discussed with the subject before undergoing their first scan.

How are the images delivered to the subject?

Depending on how the subject was recruited to the study (GP, radiologist, researcher) and the notification procedure of the centre/study, the subject can be given the images by the GP, radiologist or researcher.

8 Recommendations from VBIC

Based on the above, and our considerable discussions on this topic we recommend:

1. Researchers identify and report incidental findings to a radiologist.
2. A radiologist only reviews those scans referred to him/her as per (Item 1).
3. A second opinion is sought based on the recommendations from the radiologist reviewing the scan (at Item 2).
4. People can only participate in the study if they agree to the above.
5. Subjects are notified of an incidental finding via the route through which they were recruited to the study (e.g. by a GP, radiologist, or researcher).
6. The Participant (subject) consent form makes the above clear.
7. The Participant (subject) consent form includes relevant sections about potential implications of making an incidental finding, including future costs.