

Incidental Findings in MRI Brain Research Frequently Asked Questions (FAQ): A Guide for Research Participants

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An incidental finding is the discovery of a possible abnormality in the brain that is unrelated to the purpose of a research study. Some findings have no health significance; others may be medically significant and require follow-up by a physician. Here we provide answers to some Frequently Asked Questions (FAQ) about incidental findings in brain research that uses Magnetic Resonance Imaging (MRI).

1. Can a research scan show if the finding is medically significant or not?

No. Research scans are not the same as scans that are conducted for clinical screening or the diagnosis of a health problem. Researchers and their colleagues might notice an unusual feature of your brain and, if they suspect that it represents a health concern for you, suggest that you follow up with a physician for further scans or other clinical tests if needed.

2. Will researchers be looking for an unusual feature in my brain?

In some studies, research scans are routinely reviewed for incidental findings. In other studies, research scans will only be reviewed if a researcher notices something unusual. In a third kind of study, a clinical MRI scan with review by a radiologist is always conducted for screening. While MRI has not been approved as a screening test in healthy people, if it is administered as part of a research study, it could identify a problem before it causes symptoms and provide an opportunity for early intervention. However, early intervention is not useful in all situations and can sometimes be harmful. Any of these processes can provide a result that causes anxiety and inconvenience for you, but that ultimately has no medical significance. It is important that you understand both these benefits and risks. The researchers conducting the study will explain to you which process they follow and discuss these important considerations.

3. How often do incidental findings occur?

Studies have shown that approximately 1-8% (1 to 8 people out of 100) of healthy research participants have a finding on an MRI scan that might be significant and that would prompt referral to a physician for follow-up. Less urgent findings are discovered more frequently and may vary by age, gender, race and other factors.

4. Who will tell me about a finding that I need to follow up?

If a researcher notices an unusual feature of your brain, he or she may consult with a physician who specializes in looking at brain scans. The researcher, in coordination with the physician if needed, will talk with you about a finding that needs follow-up and also give you that information in writing.

5. Can I decline to be told about a finding?

You may decline to be told about a result that is not considered to be medically significant, but you may not decline to be told of a finding that the team believes requires medical follow-up.

6. What do I do if I am told that I need to follow up?

The researcher will provide you with a list of physicians you can contact for follow-up and information about how to make an appointment. The researcher will also provide the physician a copy of the research scans and a letter describing the finding if requested.

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7. Who pays for medical follow-up if I need it?

Depending on the type of study and approach to incidental findings (see Question #2 above), you may be offered another type of imaging test to determine whether the potential finding is actually present. Beyond that, you or your health insurance company would be responsible for any follow-up medical care costs.

8. Can I continue in this study if you find an incidental finding?

Your ability to continue in a study will depend on the type of study, when the finding is noticed, and the type of finding it might be. For example, some findings are consistent with swelling in the sinuses because of a head cold. Others could be serious such as a tumor or malformed blood vessels in the brain. If the finding is noticed during the study but will not interfere with the data being gathered, you may be able to continue. If the researcher is concerned that the finding will cause problems with the data being gathered, you will probably not continue in the study. This may be true even if the finding requires no follow-up, such as the case when a normal variation in brain anatomy affects the researcher's ability to compare it to others in the study.

9. Will information about an incidental finding go into my medical record?

Different institutions have different procedures for connecting the review of research scans with medical records. The researcher will explain local procedures to you. If you seek follow-up through your own physician, the finding will get into your medical record. Please also refer to the Confidentiality section of the study Consent Form for more details on how information about you is kept confidential.

10. Will you tell my doctor(s) about an incidental finding without my permission?

No. We will not give out any information about your research scan without your permission as described in the Confidentiality section of the Consent Form. If you give us written permission, we will forward the research scans and a letter about the finding to your doctor upon his or her request.

11. Will discovery of an incidental finding affect my ability to get life, disability, or health-related insurance?

The discovery of an incidental finding may affect your life, health or disability insurance. All information will be kept confidential and will not be released without your consent to the extent that the law allows. If you do not already have health insurance or cannot get health insurance, you may be subject to higher premiums. Many insurance companies ask for medical records before issuing a policy. These may contain information about an incidental finding (see above). Please check with the individual insurance companies for more information.

12. Can my participation in this study cause an abnormality in my brain?

No. Your research MRI may suggest a potential abnormality that is already in your brain but it cannot cause it.

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*** IDENTIFICATION AND MANAGEMENT OF INCIDENTAL FINDINGS IN NEUROIMAGING RESEARCH, NIMH WORKSHOP, OCTOBER 18, 2012, WASHINGTON, DC**

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