

Incidental Findings in MRI-Based Brain Research Examples for Consent Forms and Tips for Consenting Participants

When incidental findings are a possibility in Magnetic Resonance Imaging (MRI) brain research, it is important to pay special attention and develop policies on how to manage them.

Examples of written consent language and tips for consenting participants are provided here for three different scenarios for laboratories whose policy it is to:

Scenario (1): Send only suspicious scans for review

Scenario (2): Send all research scans for review

Scenario (3): Conduct and review clinical-grade scans on all participants

Regardless of the scenario, appropriate text about incidental findings should stand alone in the consent form and the topic should be clearly articulated when obtaining consent from participants for the study. Special procedures should be undertaken to determine appropriate processes for managing incidental findings in participants from vulnerable populations such as those with mental health conditions, and when participants are drawn from specific populations for which there is a cultural difference between the researchers and the participant population with respect to consent to participate in research and disclosure of results.

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Scenario (1) – Send Only Suspicious Scans for Review

Suggested Consent Form Language

Incidental Findings: The MRI in this study is being done to answer research questions. It is not the same type of study that a doctor would order to clinically screen for or diagnose a medical problem. The research scan may not show problems that may be found by a clinical MRI scan and it will not be reviewed for this purpose. However, if a potential abnormality is noticed, the scan will be reviewed by a physician who is affiliated with the research team. If the Principal Investigator and/or physician believes that the abnormality requires follow-up, the Principal Investigator, in coordination with a physician as needed, will contact you and provide you with information about how to follow up.

As MRI has not been evaluated as a screening test, we do not know if it is useful to find out about potential abnormalities that are not causing you any problems now. It is possible that you could be worried or undergo unnecessary treatment if you follow up on a finding and it is not significant to your health. Follow-up to determine if any treatment is needed for a potential problem can be costly [*Depending on site policy, may add "If another type of imaging test is required to determine whether the potential finding is actually present, we will offer this to you. Beyond that, you..."*] and your health insurance company will be responsible for the costs of follow-up. An abnormality discovered in your brain might also affect your ability to get some kinds of insurance or employment, or to return to your professional duties. While different institutions have different procedures for connecting the review of

research scans with medical records, an incidental finding could become part of your medical record if you report it or seek further evaluation in a clinical context. Please also refer to the Confidentiality section of the study Consent Form for more details on how information about you is kept confidential.

You may decline to be told about a finding that is not believed to be important to your health. You may not decline to be told of a finding that the team believes requires medical follow up. If you choose to opt out of being notified for findings that do not require medical follow up, please initial here _____.

Tips and sample language for discussing incidental findings with participants during the consent process:

- The MRI brain scans we will obtain during this study are different from the type that doctors order to diagnose a medical problem.
- We have no reason to suspect your scan will reveal any unusual findings since you met our criteria for participating in this study, however, sometimes the research scan may show something that might be a problem for you now or in the future.
- We will not routinely look for problems in your MRI, but if we notice something that may not be normal, we will send your scan to a doctor affiliated with the research who is trained to review MRI scans. If the doctor finds there is something in the scan that could be a concern for you, we will talk with you about it and give you information about how to follow up with a medical provider.
- Following up an incidental finding may lead to expensive tests and treatments that may have risks of their own. You or your insurance company will be responsible for any costs associated with following up the finding.
- Most findings noticed on research scans do not need any follow-up. You could be unnecessarily worried if a problem is suspected. In addition, the discovery of an abnormality in your brain could affect your ability to get insurance or employment, or your ability to return to your professional duties.
- You may decline to be told about a finding that is not considered to have medical significance. There is a place to initial that choice on the consent. You may not decline to be told about a finding that the team believes might be important to your health.
- Do you have any questions about what we have just discussed or from the **FAQ on Neuroimaging Incidental Findings** that we provided?

Scenario (2) – Send All Research Scans for Review

Suggested Consent Form Language

Incidental Findings: The MRI in this study is being done to answer research questions. It is not the same type of study that a doctor would order to clinically screen for or diagnose a medical problem. However, a physician trained to read MRI scans, such as a radiologist, will review all the research MRI scans for this study. If the physician finds an abnormality that may be medically important and requires follow-up, the Principal Investigator, in coordination with a physician, will contact you. They will provide you with an explanation of the finding, how to follow up, and a list of physicians available to further help you.

It is possible that you could be worried or undergo unnecessary treatment if you follow up on a finding and it is not significant to your health. Follow-up to determine if any treatment is needed for a potential problem can be costly [*Depending on site policy, may add "If another type of imaging test is required to determine whether the potential finding is actually present, we will offer this to you. Beyond that, you..."*]

and your health insurance company will be responsible for these costs. An abnormality discovered in your brain might also affect your ability to get some kinds of insurance or employment, or to return to your professional duties. While different institutions have different procedures for connecting the review of research scans with medical records, an incidental finding may become part of your medical record if you report it or seek further evaluation in a clinical context. Please also refer to the Confidentiality section of the study Consent Form for more details on how information about you is kept confidential.

Tips and sample language for discussing incidental findings with participants during the consent process:

- The MRI brain scans we will obtain during this study are different from the type that doctors order to screen for or diagnose a medical problem.
- We have no reason to suspect your scan will reveal any unusual findings since you met our criteria for participating in this study, however, sometimes the research scan may show something that might be a problem for you now or in the future.
- All scans in this research will be sent to a physician qualified to review MRI scans, such as a radiologist, to see if there are any abnormal findings in the scan.
- If the doctor finds there is something in the scan that could be a concern for you, we will talk with you about it and give you information about how to follow up with a medical provider.
- You could be unnecessarily worried if a problem is suspected but does not ultimately result in the need for medical care. An abnormality in your brain could also affect your ability to get insurance or employment, or affect your return to professional duties.
- Following up an incidental finding may lead to expensive tests and treatments that may have risks of their own. You or your insurance company will be responsible for any costs associated with following up a finding.
- You may decline to be told about a finding that is not considered to have medical significance. There is a place to initial that choice on the consent form. You may not decline to be told about a finding that the team believes might be important to your health.
- Do you have any questions about what we have just discussed or from the FAQ on **Neuroimaging Incidental Findings** that we provided?

Scenario (3)– Conduct and Review Clinical-grade Scans on All Participants

Suggested Consent Form Language

Incidental Findings: This research study is not designed to provide any information about your health. However, as required by [Institute], clinical MRI scans that provide health-related information will be performed during one of your MRI sessions, either as part of this study or another MRI study here at [Institute]. These will be done every year if you continue to participate in imaging research at [Institute]. We may also repeat them if we notice something in your research scans that may need medical evaluation. A doctor trained to read MRI scans, such as a radiologist, will review all research MRI scans. If we find an abnormality that requires follow-up, we will contact you to help answer questions and get the right follow-up care for you.

While MRI has not been approved as a screening test in healthy people, it can 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. MRI can also provide a result that causes anxiety and inconvenience for you, but that ultimately has no medical significance. It is important that you

understand these risks. (See “Neuroimaging Incidental Findings **FAQ**” for more information). Follow-up care to determine if any treatment is needed for a potential problem can be costly [*Depending on site policy, may add* “if another type of imaging test is required to determine whether the potential finding is actually present, we will offer this to you. Beyond that, you...”]. You and/or your insurance company will be responsible for follow-up costs. An incidental finding will become part of your medical record if you follow up. Please also refer to the Confidentiality section of the study Consent Form for more details on how information about you is kept confidential.

Tips and sample language for incidental findings with potential participants during the consent process:

- The MRI scans we will obtain during this study are not the type a doctor would order to decide if you were having a problem that an MRI scan might help to diagnose. However, we will obtain clinical scans on you separate from your research scans and have them reviewed by a radiologist (a doctor trained to review MRI scans) to look for potential problems in your brain.
- We have no reason to suspect your scan will reveal any unusual findings since you met our criteria for participating in this study, but sometimes clinical scans may show something that could be a problem for you now or in the future. While MRI has not been approved as a screening test in healthy people, it can identify a problem before it causes symptoms and provide an opportunity for early intervention. However, it can also 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.
- We may also ask you to return for another type of MRI scan if more information is needed. If the neuroradiologist finds there is something in the scan that could be a concern for you, we will talk with you about it and refer you to a doctor or specialist for follow-up.
- Following up an incidental finding may lead to expensive tests and treatments that may have risks of their own. You or your insurance company are responsible for any costs associated with follow-up medical care, except if you need another imaging test to determine if the finding really is there [*individual site policies apply*].
- The discovery of an abnormality in your brain may also affect your ability to get some kinds of insurance or employment, or affect your return to your professional duties.
- Do you have any questions about what we have just discussed or from the FAQ on **Neuroimaging Incidental Findings** that we provided?

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

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