UCR Incidental Findings Guide

UCR | Office of Research Integrity

This document is meant to guide investigators to describe their plans for addressing incidental findings in the Institutional Review Board (IRB) applications and informed consent process.

Incidental findings (IFs) are possible medical abnormalities that may have clinical implications and are unintentionally observed in the course of research studies but are mostly not related to the topic under study. Examples might include:

- A brain imaging study of depressed individuals reveals a potential structural abnormality;
- A study involving fractionation of normal human blood suggests a potential infection;
- A baseline study of mental status seems to indicate a psychiatric condition;
- A screening protocol for an exercise intervention identifies a cardiac insufficiency;

Incidental Findings in a study application

As part of research with human subjects, scientists and clinicians should anticipate the potential for Incidental Findings in experimental design and establish a process to handle the discovery of an incidental finding. Specifically, the Office of Research Integrity (ORI) requires that a pathway for managing any incidental findings be fully transparent and addressed as part of the study application and the Informed Consent Process.

Defining the Incidental Finding: Although the actual finding may not be known, the potential for incidental findings should be defined and described in the IRB *Application for Human Subjects Research.* For example, if a study involves pathogen testing on blood samples, a potential finding could be the discovery of an infection.

In some cases, incidental findings may not be relevant, such as some neuroimaging modalities that, by nature of the protocol, do not generate images that are clinically interpretable. These can include imaging protocols that are not designed to acquire clinically useful data such as functional magnetic resonance imaging (fMRI). For these instances, investigators should provide a rationale for why incidental findings are not pertinent to their study.

Management Plan: Researchers must include details in their IRB application on how the research team will handle occurrences of incidental findings. Details should include the following:

- Incidental Findings should be addressed specifically in consent forms with disclosure of a pathway for follow up and cost of handling this finding
- It is the responsibility of the research team to make the subject aware of a potential finding
- The subject or surrogate is first in line for disclosure of an incidental finding. Incidental findings will be discussed by the PI.
- Relevant study documentation will be provided to a care provider if elected by the subject.
- Verbal communication of an incidental finding should be done in a timely fashion, and documented in writing by a letter that draws on the informed consent language below.

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Recommended Consent Form Language: For all studies with incidental findings, the following text should be included as part of the informed consent form(s): (Amend highlighted text in brackets to suit research purposes. No additional language may be otherwise added, modified or deleted without express permission from the Institutional Review Board.)

> This [MRI, fMRI, EEG, EKG, Blood draw, etc.] is done for research purposes only. The [MRI, fMRI, EEG, EKG, Blood draw, etc.] test or scan being done is designed to answer research questions, not to medically examine you or provide a clinical diagnosis. The [MRI, fMRI, EEG, EKG, Blood draw, etc.] test or scan is not a substitute for one a physician would order. It may not show problems that would be picked up by a medical [MRI, fMRI, EEG, EKG, Blood draw, etc.] test or scan. The researchers are not professionally qualified to act as your medical provider. However, if we see something unusual in your scan, we will inform you so that you can obtain appropriate follow-up evaluation by your physician. We will also provide you or your physician with a copy of the scan results upon request. Any follow-up evaluation or treatment that you seek will be at your own expense. Even if your physician rules out any problems, you may be unnecessarily worried if a problem is suspected.

ADDITIONAL REQUIREMENTS FOR MRI STUDIES

As part of the Office of Research Integrity (ORI) requirements for managing any incidental findings there are additional specific processes and information that should be included as part of the IRB application and Informed Consent documents.

Subject Screening & Inclusion/Exclusion Criteria for MRI studies

The following guidelines reflect standard procedures accepted by UCR for studies involving magnetic resonance imaging (MRI), as well as how such procedures should be described within the study protocol narrative.

- Because of the high magnetic field of the MRI scanner, individuals with pacemakers, cosmetics, or certain metallic implants in their bodies must be excluded.
- Each potential subject must fill out a questionnaire to identify these and other possible contraindications to MRI scanning.
- Also, because the MRI scanner attracts certain metals, precautions must be taken to remove metallic objects from the MRI room. As an additional measure of protection, a metal detector should be in place to screen subjects before entering the scanner.

Pregnancy Exclusion: Because the risks to a fetus from MRI are unknown at this time, it is the policy of UCR that for all studies involving MRI, or fMRI, women of childbearing potential should be excluded from the study if a pregnancy test is positive or if the subject or her parent thinks that she might be pregnant, as appropriate. Studies utilizing this type of resonance imaging must include this type of information in both the study application and the consent.

Risks: Studies that utilize this type of resonance imaging should have additional precautions listed under the "Risks" section of both the IRB application & Informed Consent Form. Those documents should include information that the MRI scanner attracts certain metals and could move metallic objects within the MRI room, which might harm a subject. It should also note that individuals with pacemakers, heart rhythm disturbances, permanent cosmetics, or certain metallic implants will be excluded, as will those with a medical diagnosis of claustrophobia.

The risk section of the IRB *Application for Human Subjects Research* should also discuss that although MRI scanning itself is painless, subjects may experience discomfort. Some people become claustrophobic inside the magnet. Also, subjects may be bothered by the beeping and hammering sounds made when the scanner is collecting measurements, and/or experience peripheral stimulation, manifested as a gentle tap or sensation of mild electric shock.

Measures to minimize risks/discomforts: The IRB application should provide and indicate the following:

1. Screening procedures will be used to exclude any subjects who have metallic objects in their bodies, have a history of claustrophobia, or have other MRI contraindications.
2. Subjects will be informed that they may terminate the session whenever they feel discomfort for any reason. During MRI scanning, subjects will be able to communicate with the investigators via an intercom system, so that any anxiety or discomfort can be immediately addressed and scanning aborted if necessary.
3. Disposable earplugs or other ear protection will be provided to diminish the noise. Currently unknown risks/discomforts: Per discussion above, as a precautionary measure to guard against unknown risks to fetuses, pregnant women must be excluded from participation.

Recommended Consent Form Language for MRI studies only

In addition to the above *Recommended Consent Form Language,* studies specifically utilizing magnetic resonance imaging should also include the consent information listed in this section. The following informational paragraphs reflect commonly used language in UCR consent forms for studies involving MRIs. These statements should be amended or adapted as necessary for other MRI techniques. All consent statements should accurately reflect the procedures described in the protocol.

> Procedures: An MRI is a test that uses a magnetic field and pulses of radio wave energy to make pictures of organs and structures inside the body. If you agree to participate, you will be asked to complete a screening form. This screening form contains questions to help us figure out if you can safely participate in this study. Also, because the risks to an unborn baby are not known, we **have to make sure that females of child-bearing age are not pregnant.** Following completion of the screening procedures, you will be asked to have an MRI scan. You will be asked to lie down on a bed that can be slid into the center of the magnet. A plastic coil will be placed around your head and foam pads will be placed to help keep your head still during the scan. You will then be slid into the magnet and asked to lie still for about [ ] minutes. The MRI machine will then create images of your body. At different points during this scan, you will be asked to perform certain tasks [provide description]. You will be given a break from doing these tasks every 5-10 minutes. You can take breaks more frequently if you want.

Risks: While there are few risks from MRI and the scan is painless, this study may involve some minor risk and discomfort. You may be bothered by the loud sound the machine makes, such as beeping or hammering. Disposable earplugs will be given to you to help lower the noise. Also, some people may become fearful of being inside the small space while inside the scanner. People who have a history of this, known as claustrophobia, will not be asked to participate in this study. You may also feel a gentle tapping or a sensation of mild electric shock. During the session, we will still be able to talk with you via an intercom. If you feel uncomfortable and don't want to participate anymore, please let us know and we will stop the scan. The magnets in the MRI are very strong and will attract any metal brought into the room. You must be careful to leave any metal objects outside the room. People who have pacemakers, heart problems, or certain metal implants cannot participate. Make-up that has metallic pieces in it, such as nail polish or blush, should not be worn because it could cause irritation.

This scan is part of a research study and is not supposed to provide the same kind of examination that your doctor can do. However, if the study team finds something unusual on your scan, you will be notified and your scan can be sent to your family doctor upon your request.

ORI Determination of Risk/Review Level:

Depending on the level risk to participants, studies may be reviewed by a fully convened IRB meeting (full board review) or via expedited review processes. This determination will be made by the IRB. For additional information regarding minimal risk, you can visit the ORI Forms page and review the minimal risk tip sheet.