Title:	Management of Incidental Findings in Research Imagining		
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1 PURPOSE

To provide guidelines for management of incidental findings in research imaging.

2 PROCEDURES

2.1 Guidelines

There is the inherent risk that incidental findings (IF) may be discovered on research-directed imaging procedures. These IFs may or may not be of clinical significance. The incidence of detected abnormalities when imaging varies depending on a number of factors including age of subjects, health status, the technology used and the expertise of the individual reviewing the image. Potentially significant incidental findings have been reported to occur in 2-10% of imaged subjects. To address these issues, the National Institutes of Health (NINDS, NIDA, NIBIB, NIMH, NIA) and Stanford University co-sponsored a workshop January 2005) that focused on key areas related to brain incidental findings. This UNC policy seeks to implement this group's recommendations, with special focus on these:

1. In any imaging research, scientists and clinicians should anticipate the potential for Incidental Findings (IFs) in experimental design and establish a process to handle the discovery of an incidental finding.
2. Institutional Review Boards (IRBs) should require that a pathway for managing IFs be fully transparent and should be addressed in the IRB review.
3. The procedure for handling an incidental finding must be made explicit to all participants in the research project in the informed consent.

2.2 Options for Review and Disclosure of Incidental Findings

In the Initial Review Application, the PI should indicate which of the following options is being proposed.

2.2.1 **The PI and IRB feel it is unlikely that clinically significant abnormalities will be present:** (e.g. healthy volunteer subjects with incidence of clinically significant IF similar to health population) then the images do not need to be routinely reviewed by a board certified clinical radiologist credentialed by UNC Health Care.

Many subjects anticipate or expect that if images are obtained, the images would be reviewed for abnormalities, and this may be a form of inducement to participate. It should therefore be made clear to the subject via the consent form and verbal reinforcement that the images will not be formally reviewed by someone qualified to clinically interpret the imaging, and the purpose of their participation in the research study should not be to obtain medical information. Even though there is no routine review of images, in some cases, the PI or technician may become aware of an abnormality that may be of clinical significance. In this case, the PI should consult a board certified clinical radiologist credentialed by UNC Health Care. The subject should not be informed about the possibility of an abnormality immediately after the scan(s) in order to eliminate any risk of creating anxiety prior to review of the scan(s) by a qualified radiologist. The consultation pathway should be outlined in the IRB application and well as how the subject will be notified.

2.2.2 **The PI and IRB feel that the incidence of clinically significant incidental findings is higher than in the general population** (e.g., subjects with known disease(s) that may affect the body part being imaged) then all images should be reviewed by a radiologist credentialed at UNC Health Care or other qualified reviewer. This consultation pathway should be outlined in the IRB application and consent documents.

2.2.3 **If the imaging findings will be used as exclusion criteria or primary study endpoints** then a more detailed review and report of images may be required. In this case a radiologist credentialed at UNC Health Care or other qualified reviewer should be included as an investigator on the study and identified by name.

2.2.4 **If a central reading facility is used, such as in a multisite trial**, the PI should include in the IRB application a description of this process. The IRB application and consent documents should include information regarding whether there will be expert review of images, and should include a description of whether and how the central readers will communicate incidental findings to the PI and subsequently to the subject.

2.3 **Procedures for Review of Imagining and Disclosure**

If images will be read by a qualified reviewer and incidental findings will be reported to subjects, the following procedures should be followed.

2.3.1 Clinically significant results should be reported to subject or legally authorized representative in a timely fashion.

2.3.2 The communication should be made by the qualified reviewer or the PI (if adequately qualified to discuss findings) directly to the research subject, and/or to the subject's primary care physician (with subject's permission).

2.3.3 The communication can be oral or in writing with a record kept in the subject's research file.

2.4 **Informed Consent Process when Research Involves Imaging**

The consent process for research studies involving radiological imaging should address the following issues:

2.4.1 The possibility of incidental findings, and the potential benefits/risks of disclosure of incidental findings.

2.4.2 That research images cannot be assumed to be of clinical quality and, therefore, cannot substitute for a clinical evaluation. Subjects experiencing symptoms for which clinical imaging may be appropriate should be advised to see their primary care physician.

2.4.3 Whether research subjects will be informed of incidental findings. If subjects will be informed of clinically significant findings it should be clear in the consent that the subject agrees to be contacted and informed of the findings. The consent process should inform subjects of the potential risks involved with incidental findings which include anxiety, cost of further clinical evaluation, finding becoming part of their medical record, etc.

2.5 Sample Consent Language

2.5.1 Use when study images will *not* be routinely reviewed by an expert:

Possible Discovery of Findings Related to Medical Imaging

The [MRI, CT, X-ray, etc.] we are using in this research study is not the same quality as a [MRI, CT, X-ray, etc.] that you may have as part of your health care. The images from the [MRI, CT, X-ray, etc.] will not be reviewed by a doctor who normally reads such images (such as a radiologist). As a result, you may not be informed of any unexpected findings. The results of your [MRI, CT, X-ray, etc.] will not be placed in your medical record.

Occasionally the technologist or principal investigator may notice something abnormal on the imaging. If this does occur, the images will be reviewed by a qualified radiologist to determine if there is anything of clinical importance. If something is found to be important then you, and/or your primary care provider will be notified. Any further follow up and costs associated with the incidental finding will be your responsibility. There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as problems with getting insurance or a job, or feeling worried about a finding for which no treatment is required or appropriate).

<u>For "Healthy Volunteer Studies", you may include</u>: Do you wish to be informed in case of clinical/relevant unexpected findings? (With yes/no option)

2.5.2 Use when study images will be routinely reviewed by an expert:

Possible Discovery of Findings Related to Medical research Imaging

Whenever imaging [MRI, CT, X-ray, etc.] is done, there is the chance of finding something unexpected. Unexpected findings can have clinical significance, or no clinical significance. Clinically significant means that the [MRI, CT, X-ray, etc.] shows a problem that may or require further follow up or treatment. The imaging studies in this study will be reviewed by a qualified radiologist. You will be informed of any findings of clinical significance that may be discovered during the imaging procedure.

There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as problems with getting insurance or a job, or feeling worried about a finding for which no treatment is required or appropriate). The [MRI, CT, X-ray, etc.] we are using in this research study is not the same quality as a [MRI, CT, X-ray, etc.] that you may have as part of your health care. If you believe you are having symptoms that may require clinical imaging, you should contact your primary care physician.

<u>If the images will be reviewed by a central reader, include the paragraph below:</u>

While your [MRI, CT, X-ray, etc.] will be conducted here at UNC no UNC physician will review the [MRI, CT, X-ray, etc.]. Rather, your images will be reviewed by a "central reader", a physician designated by the sponsor of this trial to review all of the images. We will inform you of any findings of clinical significance that the central reader tells us about.

3 DEFINITIONS

Incidental Finding: Unexpected imaging finding discovered in the course of conducting a research study that has a potential health or reproductive importance that are beyond the aims of the study and have not been anticipated in the study protocol. Such procedures may include MRI, CT scans, Ultrasound, PET, SPECT, arteriograms, x-rays, fluoroscopy, or other tests that produce an image.

Clinical Significance: Practical importance.