COLUMBIA UNIVERSITY INSTITUTIONAL REVIEW BOARD POLICY

INCIDENTAL FINDINGS FROM IMAGING PROCEDURES CONDUCTED FOR RESEARCH STUDIES

Issued: August 7, 2012
Revised: March 26, 2015

I. SCOPE

This Policy sets forth IRB policy with respect to planning for and handling incidental findings in research studies conducted by Columbia University investigators that include certain imaging procedures as outlined in this Policy.

The following studies will be subject to this Policy: (a) studies initially reviewed by the IRB after August 7, 2012 and (b) studies initially reviewed by the IRB prior to August 7, 2012, but modified after March 26, 2015, to include or revise (e.g., type, number, target accrual) imaging procedures that produce Required Review Images (as defined in Section III below).

II. BACKGROUND

For purposes of this Policy, an **incidental finding (IF)** is a finding concerning an individual research subject that has potential health importance and is discovered in the course of conducting research, but is beyond the aims of the study.

Advances in imaging technology have produced new diagnostic capabilities with improved accuracy and potential new treatment mechanisms. As a result, there has been an increased use of imaging techniques in human subjects research. In the course of such research involving imaging, investigators may gather information about a subject that is not pertinent to the research study, but may have important clinical implications for the subject. The incidence of IFs is widely variable, depending on a number of factors, including the technology used and the age and health of the subjects. There are no current federal regulations or generally accepted national guidelines that specifically deal with IFs in research.

An IF may be discovered not only in collecting and analyzing research images and data during a study, but also in screening procedures to determine whether a potential subject qualifies for inclusion in the study population or in collecting baseline physiological information.

The IRB believes that guidance is necessary as to how certain observed IFs will be managed by investigators and members of the research staff and how plans for handling such IFs will be presented to potential research subjects during the informed consent process.

III. POLICY

This Policy applies only to studies **(IF Studies**) conducted by Columbia University investigators in which the imaging procedures produce high density images that provide anatomic or physiological data of the type that is used in clinical diagnosis or treatment, including, but not limited to, MRI scans, CT scans, PET scans and X-rays (**Required Review Images**). The IRB will consider this Policy in reviewing protocols for such studies, but will determine the specifics of how IFs should be handled in the context of each particular study.

Required Review Images must be read for IFs by a radiologist credentialed by the Department of Radiology (a **Credentialed Radiologist**) unless there is a justification for why such review should not be required. If the scan required by the protocol is performed for clinical purposes in accordance with the standard of care (an **Excepted Scan)** and such protocol already provides for readings of Required Review Images by a Credentialed Radiologist, neither an additional reading under this Policy nor the inclusion of the information outlined in Section B below in the applicable consent documentation is required.

An imaging study that is expected to have clinical relevance in the subject population – e.g., brain scans in subjects with dementia or stroke – will usually necessitate full clinical review, rather than one merely for IFs.

The Credentialed Radiologist will give notice to the Principal Investigator (**PI**) if the Credentialed Radiologist believes that there is an IF of Clinical Significance.

An **IF of Clinical Significance** in the context of this Policy is either a Class A IF or a Class B IF.

A Class A IF is one that reveals a condition that is likely to be life-threatening or severe. Examples from brain imaging include acute infarct, acute hemorrhage (e.g., SAH, SDH, hematoma), mass with prominent edema or brain compression (intra or extra axial), acute hydrocephalus, aneurysm, other vascular malformation (e.g., cavernous or AVM), mass or infiltrating lesion with minimal edema or mass effect (e.g., glioma, small possible metastases) and possible acute demyelinating or inflammatory (e.g., Lyme) disease with enhancement.

A Class B IF is not necessarily immediately life threatening or severe, but is likely to be deemed by a subject to be important to his/her health. Examples from brain imaging include acute sinusitis (with air/fluid levels) or mastoiditis, non-specific patchy white lesions in subjects less than 60 years of age (chronic ischemia, demyelination, infection or inflammation in periventricular white matter, basal ganglia or pons), chronic infarct, chronic trauma, tonsillar ectopia, severe generalized atrophy, focal atrophy (e.g., isolated brain stem and/or cerebellum), small meningitis (<3cm) without edema or cranial nerve or brain stem involvement and possible demyelinating disease (non-enhancing).

The review by the Credentialed Radiologist will occur as soon as possible but no later than two weeks following receipt of the image. The timing of the notice from the Credentialed Radiologist to the PI should be consistent with the suspected severity of the finding.

If imaging procedures covered by this Policy take place at a non-Columbia facility, the PI will arrange for the images to be sent to him/her, and all Required Review Images will be reviewed by a Credentialed Radiologist at Columbia unless the non-Columbia facility has equivalent standards and protections to those outlined in this Policy.

Unless otherwise authorized by the Department of Radiology, imaging done at Columbia must be reviewed by a certified radiologist at Columbia.

A. INFORMATION TO BE INCLUDED IN THE PROTOCOL

The protocol for each IF Study should include the following information:

1. the possibility of identifying IFs in the research process, whether the potential for discovering IFs can be quantified, and the kinds of IFs that may be revealed;

2. documentation from the Department of Radiology confirming that review by a Credentialed Radiologist will occur as soon as possible, but no later than two weeks following receipt of the image; and

3. a plan for notifying the subject of an IF of Clinical Significance. Communication with the subject is the responsibility of the PI. However, if the PI is not a physician or is otherwise not qualified to discuss the IF with the subject, such communication should include a medical professional who is knowledgeable about the type of IF found and who is experienced in communicating sensitive medical information. Communication may be initially verbal, followed by a written communication. The subject should have the opportunity to have questions answered. The time frame of the initial communication with the subject should be consistent with the suspected severity of the finding. Investigators should obtain appropriate contact information for the subject.

B. INFORMATION TO BE INCLUDED IN THE INFORMED CONSENT PROCESS AND DOCUMENTATION

During the informed consent process for an IF Study, the person obtaining the consent and the consent documentation should specifically address the following topics in appropriate lay language, to the extent applicable to the study, for all scans other than Excepted Scans. The IRB provides sample consent language for the below items.

1. That, although the study scans are being undertaken for research purposes only, an IF may be detected;
2. An explanation of what an IF is;
3. That the study scan will be reviewed by a radiologist;
4. An explanation of what an IF of Clinical Significance is and that an IF of Clinical Significance will be disclosed to the subject promptly. The disclosure may be made by a medical professional rather than the PI if the PI is not a physician;

5. That if the subject so desires, his/her physician will also be notified by the PI if an IF of

Clinical Significance is found. If the subject does not have a private physician, the PI will refer him/her to an appropriate clinic; and

6. That if an IF of Clinical Significance is found, the subject will decide whether to proceed with further examinations, tests, and/or treatments and the subject or his/her insurer will bear any costs of such further examinations, tests or treatments.

C. POST IRB APPROVAL REQUIREMENTS

Findings of IFs of Clinical Significance and the management of such findings should be documented in the research records for the study.

At the time of a continuing review of an IF Study in which an IF of Clinical Significance has been reported to the PI, the PI should provide the IRB with the following information via the Reporting of Incidental Findings Form: the number of Required Review Images, the subject's study number, the type of scan, the date of the scan and a description of the IF of Clinical Significance. In addition, the Principal Investigator should indicate the date of communication with the subject and the outcome, if known, for each Incidental Finding.