# University of Minnesota Center for Magnetic Resonance Research Standard Operating Procedure Incidental Finding Review Process

SOP Number / Version: SOP006 / Version 1

Approval Date: 15 May 2012

Implementation Date: 30 May 2012 Author/Owner: Jeramy Kulesa

Approval Signatures	Date
Author/Owner:	
Regulatory Compliance Coordinator:	
Center Director:	

## 1 Purpose

The purpose of this procedure is to define the process for submitting, tracking and following-up on any potential abnormal imaging results within the Center for Magnetic Resonance Research.

#### 2 Scope

This procedure will apply to all personnel who are involved in conducting human subjects' research at CMRR who have indicated in their IRB protocols that they would refer abnormal findings to a Radiologist for review.

#### 3 Definitions

**Communication Plan** – Process by which radiologist communicates to researcher via online portal regarding findings and next steps. All of which should be recorded in the online portal.

**Escalation** – Process in which radiologist indicates that a research subject should follow up with their primary care physician. Scans that are escalated require that the research team confirms that recommended follow-up was communicated to subject.

**Incidental Findings Scan Review** – Online portal that is used to request scan review

**PACS** – Picture Archiving and Communication System, online portal that images must be uploaded by researcher / MRI Tech in order for radiologist to review and complete incidental scan review.

### 4 Responsibility

It is the responsibility of all personnel who perform the functions listed in Section 2 to adhere to this SOP.

#### 5 Procedure

The incidental finding review system gives the researcher a way to request a high-level radiologist review if they observe something unusual in a scan that may need medical attention. Radiologists review the scans for a reduced fee, and only include a brief summary of their findings and indicate whether or not the subject should be referred to their primary care physician for follow-up.

#### 5.1 Process Flow Overview

It is the responsibility of the Investigator scanning the volunteer subjects to review imaging data to determine if a particular set of images shows an abnormal result.

#### 5.2 Details Siemens Systems (3T's, 7T's and 10.5T)

Send images for review to RAD\_READ. For brain imaging studies send only MPRAGE sequence. Submit request for Radiologist Scan Review via CMRR website: <a href="http://www.cmrr.umn.edu/scanreview//">http://www.cmrr.umn.edu/scanreview//</a> Include a detailed description of the images in question and pertinent medical history. If immediate review is necessary call the Fairview neuro reading room at 612-273-3547.

## **5.3** Details 4T and 9.4T

Email images with a suspected abnormality in a TIFF or a JPG format to welvenda@umn.edu. Submit a request for Radiologist Scan Review Request on CMRR website: <a href="http://www.cmrr.umn.edu/scanreview//">http://www.cmrr.umn.edu/scanreview//</a> Include a note indicating that the images have been sent via email, a detailed description of

the images in question and pertinent history. If immediate review is necessary call the Fairview neuro reading room at 612-273-3547.

## 5.4 Review of Potential Abnormal Images by Radiologist M.D.

Periodically, at minimum weekly, a radiologist or resident will review all pending potential abnormal submissions, and will communicate via the CMRR Research Scan Review system whether follow-up is required. The Principle Investigator will receive a message from the scan review system that the images have been reviewed. If the radiologist determines that medical follow-up is required, a report of abnormal finding will be noted in the Research Scan Review notes for the particular imaging event.

#### 5.5 Assurance of Timely Review by Radiologist.

All scan reviews will be completed within 7 days of submission.

#### 5.6 For Urgent scan reviews

If an immediate review is needed call the neuro reading room at <u>612-273-3547</u>. Provide the following information:

- 3T, 7T and 10.5T send the images to RAD\_READ
- 4T and 9.4T call the radiologist and ask what email address to send TIFF or a JPG images to. Cc images to welvenda@umn.edu
- Direct the radiologist to log into the Radiologists Scan Review at http:<u>http://www.cmrr.umn.edu/scanreview//</u> The radiologist login is the x500 user name and password. After reviewing the images the radiologist must complete the scan review document.
- The radiologist will instruct you what to do with the subject (i.e. send home or to the hospital)
- Send an email to welvenda@umn.edu detailing the outcome.

#### 5.7 Follow up with Research Volunteer

The Principal Investigator will be alerted via email that the radiologist has finished the review and that notes are available. If the notes state that follow up is recommended, the investigator will determine the identity of the volunteer, and contact the individual to recommend consultation with a primary care provider.

At no time should the investigator discuss the findings or medical conditions with the volunteer.

# **6** Forms and Templates

N/A

# **7** Appendices / Tables

N/A

# **8** Revision History

Version	Approval Date	Change from Previous Version		
Number				
1	15 May 2012	Original Version		