

IF Checklist: Who Does What When

Before the study begins: Prior to an IRB protocol being submitted to the IRB, the principal investigator (PI) of a study involving MR scans at ZMBBI will send a form letter to Stephen Dashnaw in Radiology requesting Incidental Findings (IF) reads. Stephen Dashnaw in Radiology will countersign the letter and return it to the PI. The PI will submit the signed letter to the IRB with his/her protocol. The PI also determines who their designated lab member is to add new records and retrieve reads in RedCap.

At the scan: the Level III operator must push the structural MR sequences directly from the scanners to the Radiology research PACS (RADIO) for reading by the assigned radiologists.

At the scan: a designated lab member responsible for imaging will login to RedCap and will “Add a New Record” by completing the information necessary for review. The radiologist will review each MR scan and complete the “Read” part of the form as soon as possible, but no later than 10 business days after receipt of the sequences.

Within 10 business days of the scan: a designated lab member retrieves the read from Redcap. If a read has not been completed in the required time, or an expedited read is required, then the designated lab member should notify Stephen Dashnaw. ZMBBI will take care of billing for radiology reads.

If there is an incidental finding (rated Level 2-4; see “Incidental Finding Levels” on p 2): the PI calls the participant to communicate the finding and provide advice on the next steps they should take.

Alternately, the PI can pay an MD \$250 to research the finding and call the participant. In this case, the PI emails the radiology read (in the form of an anonymized PDF) to the MD. Neurology residents who’ve agreed to make the calls:

Name	Email	Phone
Francesco Michaelassi	fem2104@cumc.columbia.edu	773-848-2739
Brian Fidali	bf2419@cumc.columbia.edu	336-287-4951
Jeremy Ader	ja3296@cumc.columbia.edu	914-450-2696
Eva Franzova	ef2504@cumc.columbia.edu	607-342-8461
Christoferos Koumas	ck2967@cumc.columbia.edu	347-371-2550
Amol Mehta	am4677@cumc.columbia.edu	240-478-7691
Sean Marinelli	sm4091@cumc.columbia.edu	646-899-2809

The PI also calls the MD to provide the identity and contact information of the subject. Both the email and the phone call are required. Participant contact information cannot be emailed.

The MD commits within 2 days to making the call and sending out the letter within 7 calendar days. If they can’t commit, the PI contacts another of the neurology residents.

Once they commit, the MD takes the following steps: taking 15 min time for research on the finding so as to be able to communicate the finding well and point the subject to the most relevant resources and services, taking 10 min to draft a version of a form letter with relevant details, sending this to the participant via registered mail or email, and taking up to 15 min to talk to the subject. Last, the MD informs the PI and the MR Research Administrator that this has been completed.

The PI awaits confirmation that the phone call has happened. If the MD doesn't confirm within 1 week, the PI follows up with the MD. \$250 will be charged to the PI's grant to pay the MD after the MD submits proof of email or registered mail letter to the MR Research Administrator.

The PI submits an IRB amendment with the finding.

Incidental Finding Levels

Level 1 – No medically significant findings (normal or normal variant findings) No medical follow up needed. This includes research subjects older than 60 years with atrophy and chronic microvascular ischemic changes (e.g. periventricular white matter, basal ganglia or pons).

Level 2 = Class B IF (minor findings) The subject should discuss the medical significance of these findings with his/her physician, but no specific time frame is recommended. No immediate medical attention is needed.

Level 3 = Class A-2 IF (abnormal findings) Expedited medical evaluation within two weeks is recommended for further evaluation of these findings.

Level 4 = Class A-1 IF (acute abnormal findings) Immediate medical evaluation needed today (e.g. emergency room)

EXAMPLES:

A **Level 2 or 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 infarct, chronic trauma, tonsillar ectopia, severe generalized atrophy, focal atrophy (e.g., isolated brain stem and/or cerebellum), small meningioma (<3cm) without edema or cranial nerve or brain stem involvement and possible demyelinating disease (non-enhancing). Examples from abdominal imaging include non-obstructing cholelithiasis or urolithiasis,

A **Level 3 or Class A-2 IF** is of more medical significance and requires expedited clinical evaluation (e.g. within 2 weeks). Examples from brain imaging include 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. Examples from abdominal imaging include renal, liver, pancreatic or pelvic mass lesions, aortic aneurysm, cholelithiasis or urolithiasis with biliary or ureteral obstruction, uterine or ectopic pregnancy and spinal mass lesions. Examples from chest imaging include pneumonia, atelectasis, airway compression, cardiomegaly, aortic aneurysm and spinal mass lesions. This class of IF's is of most concern because these serious conditions may not be clinically apparent or may be associated with vague or confusing symptoms.

A **Level 4 or Class A-1 IF** is one that reveals a condition that is likely to be life-threatening or severe and that requires immediate (emergency room) or expedited clinical evaluation. 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) and acute hydrocephalus. Examples from abdominal imaging include intraperitoneal free air, acute appendicitis, diverticulitis, cholecystitis, pancreatitis, bowel ischemia or perforation and severe bowel obstruction. Examples from chest imaging include pneumothorax or hemothorax, aortic dissection or pulmonary embolus.