

The CFMRI has no formal policy or requirements regarding clinical evaluation of research MRI studies, and there is no routine clinical evaluation performed by CFMRI staff of research studies. It is left up to each PI to decide if they need their research studies reviewed for abnormalities, and to make any necessary arrangements with a radiologist themselves.

A need for further review of research MRI studies generally falls into two scenarios:

Scenario A. An incidental abnormality is spotted on the images by the PI, and they would like a professional opinion on the significance of this.

What to do:

1) Show your MRI to a radiologist

The following neuroradiologists are available if you need assistance:

- David Dubowitz MD PhD (dubowitz@ucsd.edu)
- Roland Lee MD (rrlee@ucsd.edu)
- Alternatively you may choose any radiologist of your choice (see <http://radiology.ucsd.edu> for a full list of UCSD radiologists)

2) Tell your subject

- If the radiologist agrees that there is a significant abnormality on the MRI, you should inform your subject (even though this may cause them some anxiety).
- You are much less likely to run into trouble later if you tell your subjects about their imaging findings than if you fail to tell them.

3) With the permission of your subject, suggest (or arrange) further follow-up

Depending on the recommendation of the reviewing radiologist, follow up with:

- Subject's Primary physician and/or
- UCSD Radiology

4) \$\$\$ - inform your subject that there may be additional costs associated with follow-up.

- Costs associated with incidental findings are the responsibility of the research subject
- These costs are not covered by UCSD, and are not budgeted in the research study

5) Pay the radiologist

- Most radiologists will not charge for an occasional opinion, but if you require studies reviewed on a more regular basis there is likely to be a charge (typically \$70-100 per study).

Please note: there is no routine clinical over-reading service at CFMRI. Although the CFMRI will assist PI's in locating a radiologist if they need one, all arrangements to review MRI studies are a private arrangement between the PI and a radiologist of their choice.

Scenario B. The research plan calls for a full diagnostic MRI exam to be performed in parallel with the research MRI studies.

What to do:

1) Discuss your MRI needs with a radiologist:

This is a common scenario if your subjects are part of a particular patient group. It is important to discuss your needs early on with a radiologist (i.e. when you design your study), as the MRI sequences to be used will depend on the exact clinical questions to be answered. A private arrangement should be made with a radiologist to review and provide a report of the study.

The following neuroradiologists are available for advice on suitable MRI imaging sequences, and to review and report diagnostic brain MRI exams:

- David Dubowitz MD PhD (dubowitz@ucsd.edu)
- Roland Lee MD (rrlee@ucsd.edu)
- John Hesselink MD (jhesselink@ucsd.edu) (Note: not taking on any new work)
- Rosalind Dietrich MD (rdietrich@ucsd.edu) (Note: not taking on any new work)
- Alternatively you may choose any radiologist of your choice (see <http://radiology.ucsd.edu> for a full list of UCSD radiologists)

2) Arrange for the radiologist to review your images:

Images may be reviewed at the scanner console at CFMRI, but this is usually not convenient as studies are cleared from the database regularly, and most radiologists are located offsite. It is often more convenient to have your study uploaded for a radiologist to review off site. Discuss the following options with Eman Ghobrial at CFMRI (eghobrial@ucsd.edu):

- Upload to a remote work station (teleradiology)
- Upload to the hospital network (PACS)
- Private arrangement (e.g. review images on CD)

3) Pay the radiologist

Typically this costs \$70-\$100 per study (depending on complexity). Payment options include:

- Pass-through recharge via CFMRI
- Include radiologist as % personnel on your grant
- Private arrangement

Additional things you and your subjects should know.....

1) Research MRI is not a diagnostic study

e.g A typical clinical brain MRI exam may include the following sequences:

Sagittal T1	Axial Diffusion
Axial T1	Coronal T2
Axial FSE T2	Axial Gradient echo
Axial FSE FLAIR	

It may also include additional sequences:

Fatsat sequences
MR spectroscopy
MR angiography/venography
Gd contrast / perfusion

By comparison, a typical research fMRI study may include only the following sequences:

3D T1
Axial EPI

The limited set of sequences used for a research MRI study is generally inadequate to characterize any abnormality seen or to make a diagnosis. Your subjects should be made aware of these limitations:

- A research MRI does not substitute for a diagnostic MRI
- Even large abnormalities may be missed
- If an abnormality is detected it may still not be possible to determine if it is significant or not
- Finding no abnormalities on a research MRI may be misleading (false negative error)
- Primary review of the MRI is by the PI – studies are not routinely reviewed by a radiologist

2) Anticipate the possibility of incidental MRI abnormalities

- Normal subjects may have undisclosed motivation to seek out a MRI exam (e.g. previous head injury, family history of brain tumor, headaches or other symptoms).
- Subject often volunteer for a research study specifically for the free (research) MRI exam

3) Report all (radiologist confirmed) abnormalities to your subjects

- When consenting your subjects, inform them they will be told if their MRI is abnormal
- Provide a verbal report of their imaging findings in a timely manner. Follow this with a written description of any positive findings.
- Obtain your subject's consent before informing their primary physician

4) Warn subjects

- Follow up diagnostic imaging will cost \$\$\$
- Insurance companies expect patient to present with a "symptom" not an "incidental MRI finding" (which may lead them to characterize the abnormality as "pre-existing")
- Pre-existing conditions may not be covered by health insurance
- Incidental findings may impact your subject's ability to get life insurance or health insurance in the future

5) IRB requirements

- UCSD HRPP has very specific requirements for the wording of informed consent. Please contact HRPP or visit their website (<http://irb.ucsd.edu/>) for the latest guidelines.
- For some studies, HRPP have asked PI's to detail in their protocol how incidental abnormalities will be managed:

Please feel free to use/modify the following paragraph in your IRB submissions:

"...All research MRI studies will be reviewed by the PI. Any suspected abnormalities will be discussed with Dr. xxx, an attending radiologist at UCSD Medical Center. If an abnormality is confirmed, the subject will be informed, and they will be advised to contact their primary physician for further evaluation..."

6) Further Reading

Judy Illes et al. Practical approaches to incidental findings in brain imaging research. *Neurology* 2008;70(5):384-390 <http://www.ncbi.nlm.nih.gov/pubmed/18227420>