



PRESENTED AT

RSNA 2010

PERSONALIZED MEDICINE:
In Pursuit of Excellence

CTSA IWG Session

Tuesday, November 30th, 3:30 – 5:30 pm



PERSONALIZED MEDICINE:
In Pursuit of Excellence

Part 2:
**How to Get Clinical Trial Studies Read
by Radiologists: *Models and
Reimbursement***

Panel Discussion

Are there institutional policies requiring Radiology review of clinical protocols?

Cornell	Harvard	Hopkins	U New Mexico	Ohio State	U Penn	Wash Univ.	Duke
Not beyond usual IRB / RSC review. Office of Imaging Protocol Development and Review. Use is optional.	Yes. Via IRB protocol submissions.	Yes IRB required Radiologist on review board.	Yes. Radiologist on Medical Scientific Review Committee.	Not yet.	Yes, if they use imaging core research facilities. Image interpretation is not mandated.	Yes. Radiologist must be "engaged" - IRB required.	Yes, if imaging is in Consent Form.

How is the commitment for research reads between PI and individual radiologists structured (e.g., hourly fee, percent effort) ?

Cornell	Harvard	Hopkins	U New Mexico	Ohio State	U Penn	Wash Univ.	Duke
Various Study fee; Time and effort; Other arrangements.	Fee per scan (\$25-\$60/scan) % effort Fee allocated to radiologist's department.	% effort Fee for service based on CPT codes.	On-duty radiologist. At time of clinical read. Back-up Chief of Oncology Imaging .	Case charge based using a core lab	Either direct contracting from the PI, or though a core reader service provided by the imaging core facility.	% effort Clinical service: any radiologist, individually negotiated fee Incidental findings set fee.	Based on prorated hourly rate.

What are payment mechanisms/fees ?

Cornell	Harvard	Hopkins	U New Mexico	Ohio State	U Penn	Wash Univ.	Duke
Various. Standard fee schedule, discounts are possible based on sponsor, academic interest.	Contract to include funding for TIMC. Fees are per-scan analysis. Two-tiered pricing based on industry vs. non-industry \$\$.	Fee schedule: 150% Medicare fee, unless a specific rate negotiated with a study PI.	\$50.00 per case (i.e. one chest/abdomen/pelvis CT)	Fee schedule	Variable	Sourcing from grant contract and fees, % effort is established up front. Paid per subject using either CPT or CPT + special Fee.	% effort or Fee per case.

Are research reads integrated with clinical reads, or are there separate arrangements?

Cornell	Harvard	Hopkins	U New Mexico	Ohio State	U Penn	Wash Univ.	Duke
Separate	Separate, but mostly captured electronically from clinical PACS SOP for discordant results.	Research arrangement with a radiologist who is a co-investigator or who is a designee for the protocol. Research over-reads part of clinical read.	Many are integrated to clinical practice. Some are off-line, documented in email or hard copy.	Separate from clinical. Specific trial protocols are developed with case charges.	Can be either depending if the images are performed as part of routine care or not.	Research reads can be integrated with clinical reads; or separate arrangements for delivery via CD, FTP, and PACS.	Separate.

Is there a Research PACS separate from the Clinical PACS?

Cornell	Harvard	Hopkins	U New Mexico	Ohio State	U Penn	Wash Univ.	Duke
Yes.	Yes for PET. In progress for CT and MRI.	Research PACS and Clinical PACS are separate; but clinical trial data on Clinical PACS.	Research cases on clinical PACS.	Research-based workstation. No research PACS; a non-clinical care PACS is considered.	In process	Separate archival system for research, a home built web-based service. Clinical PACS can be used for research.	Yes.

What is the research request mechanism (e.g., order via RIS or other)?

Cornell	Harvard	Hopkins	U New Mexico	Ohio State	U Penn	Wash Univ.	Duke
RIS for clinical over-reads. Research data reads are requested outside of the RIS.	PI submits a New Project Request Form to DF/HCC IRB, enabling selection of TIMC as a core service, online order entry for scan analysis.	Research interpretation and Research over-read requests are entered into RIS ordering system.	Exam header for a standard clinical report. E-mails to Chief of Oncology Imaging.	Reference to clinical trial in an RIS order. Pure research imaging is scheduled between coordinators.	Schedule with the research core.	Research requests via Clinical Research Laboratory, CRL works with RIS to match up with appropriate reader.	Exam order is RIS. Research read is Non-RIS. Some are by email; some by paper CRF.

How is the research interpretation recorded (e.g., research forms vs. standard clinical report)?

Cornell	Harvard	Hopkins	U New Mexico	Ohio State	U Penn	Wash Univ.	Duke
Clinical over-reads in RIS Research reads on research forms with mark-ups in Research PACS.	Web-based report, annotated images, graphs and trial summary.	Research Forms, per protocol Standard clinical report.	Both.	Special research analysis report separate from standard clinical reporting.	CRF and when required in the medical record via the RIS.	Can go directly into the clinical system, or they can be reported directly by Radiologist on form or CRF.	CRF.

Is the research read done blindly or does the radiologist have access to the clinical interpretation?

Cornell	Harvard	Hopkins	U New Mexico	Ohio State	U Penn	Wash Univ.	Duke
Research read blindly, with subsequent comparison to clinical interpretation.	Blindly. Preliminary assessment by imaging analysts. Scan and measurement is then reviewed by radiologist.	Depends on protocol, involved in the study. Perform readings accordingly. Over-read is done as clinical.	As clinical cases. No analysis (i.e. response assessment) performed routinely by radiology.	Depends on the trial and stipulations of the protocol.	Defined by protocol.	In most cases, this is done blindly, but it is project specific.	Defined by protocol.

How are incidental findings and potential liability issues handled?

Cornell	Harvard	Hopkins	U New Mexico	Ohio State	U Penn	Wash Univ.	Duke
Departmental policy, IRB adopted. All SOC research imaging routinely have clinical reads. All non-SOC research imaging have clinical over-reads.	Communication with the PI and trial personnel. FDA-approved software.	PI-responsibility to handle follow-up once notified by radiologist (documented in clinical record).	Radiologist over-reads (IRB mandate) for incidental findings that may require action.	Managed as defined by protocol. Otherwise, a subject is contacted and asked to identify a physician.	Info transmitted to Pt by research PI.	No formal report is generated, but the Radiologist informs the PI who is responsible for follow up.	PI responsibility to define process for each trial.

Other comments: