

IMAGING RESEARCHER'S WORKSHOP

ACRIN 2011

Workflow for Clinical Over-reads and
Research Data Extraction in Clinical Trials

Outline

- Institution's policy for a clinical over-read for non-SOC imaging
- Workflow management for ordering over-reads
- Workflow for extracting the research data from the imaging studies for SOC and non-SOC imaging
- Over-read service: who, when, where

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- IRB-mandates that any study that has an image with identifiable anatomy gets over-read (adopted in 2009)
- Each protocol must have a designated credentialed at JHU Radiologist named on IRB application

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Ordering research reads

- Research Requisition

The Russell H. Morgan Department of Radiology and Radiologic Science
Image Subject Research Requisition

Instructions:

1. Study coordinator completes top portion of form.
2. Study Subject must bring completed research requisition with them on date of service.
3. PSC registers the Study Subject and enters correct research study from paper database.
4. PSC or Tech does order entry selecting PAT CODE # for date of service.
5. For ALL RESEARCH, enter VTL? for ICD-9 code and track event selecting a charge modifier of 00.
6. If you have any questions, please call Gale Christensen 443-287-2676.

Subject Name: _____

Study Name: _____

Department: _____

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Liability over-reads

- RIS ordered
- Shows up on a work-list
- Routine report for extra-investigational body parts

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- Radiology services
 - Radiologist as a co-investigator, % effort (individual workflow)
 - Research read per protocol
 - Liability over-read
 - Radiologist as a designated reader, fee for service (individual workflow)
 - Selected radiologist
 - Research read per protocol
 - Liability over-read
 - 50% radiologist /50 department
 - Radiologist as a clinical provider at the time of imaging (part of clinical workflow)
 - Any radiologist
 - Liability over-read
 - 50% radiologist /50 department

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Reimbursement

- Prospective Reimbursement Analysis (*PRA*) process began in 2008.
- PRA determines what potential charges are considered standard of care or research.
- Cost information from the PRA has been included in the study consent forms, "Cost" section of the consent form references the IRPFR Sheet.
- A separate Insurance and Research Participant Financial Responsibility Information Sheet - contains information about participant costs that may be associated with research.

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DISCUSSION

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ARE RESEARCH READS INTEGRATED WITH CLINICAL READS, OR ARE THERE SEPARATE ARRANGEMENTS?

Cornell	Harvard	Hopkins	U New Mexico	Ohio State	U Penn	Wash Univ.
Separate	Separate, but mostly captured electronically from clinical PACS SOP for discordant results.	Research arrangement with a radiologist who is co-investigator or who is a designee for 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.

From RSNA 2010

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.
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 reader 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.

From RSNA 2010

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.
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.

From RSNA 2010

HOW ARE INCIDENTAL FINDINGS AND POTENTIAL LIABILITY ISSUES HANDLED?

Cornell	Harvard	Hopkins	U New Mexico	Ohio State	U Penn	Wash Univ.
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.

From RSNA 2010

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