SCOPE: All research trials must go through the standard Office for Clinical Trials approval process (including IRB approval) and all those with an imaging component must include the Radiology Checklist and receive approval from the Department of Radiology & Imaging Sciences [http://radiology.emory.edu/research/research-forms.html](http://radiology.emory.edu/research/research-forms.html).

PURPOSE: To establish guidelines and workflow for Imaging Services research exams.

PROCEDURE:

Please utilize the following guides that best suits your scenario:

1. **Patient involved in a clinical trial BUT will have imaging studies performed unrelated to the research and pertinent to their condition.** All processes will follow standard workflow procedure(s) and scanning should be done on a clinical scanner. This represents clinically-indicated imaging performed for typical clinical care of the patient.
   
   i. *If the referring physician requests something specific to the research protocol to be included in the report, the coordinator must include the comment on the order requisition. If response evaluation criteria in solid tumors (RECIST) or other read required, process will require special comments.*

      
      i. Computerized provider order entry (CPOE) located in EeMR for inpatient
      ii. Paper orders for outpatients will be scanned into the patient’s Emory electronic medical record (EeMR).
   c. Scheduling – follows EHC standard imaging scheduling process.
   d. Storage in EeMR – follows EHC standards for inclusion in the EHC medical record.
   e. Storage in Picture Archiving Communication System (PACS) – follow EHC standards for inclusion in the EHC PACS system.

2. **Research subject involved in trial and will have imaging studies relating to the research performed on a clinical scanner with a professional read to follow.** All Professional fees and technical fees are billed to the grant.

   a. Billing Process – Utilize Emory Research Management System (ERMS) billing process for Health Quest (HQ) and IDX. Cases in IDX set up with 7 day window.
      
      i. Instead of patient insurance, grant smart key should be utilized. For issues please contact the research coordinator.
   b. Ordering Process –
      
      i. CPOE for inpatient.
ii. All research orders will be submitted via a scanned and faxed Research Imaging Order form for outpatients.

iii. If imaging study does not require anything other than standard imaging protocol(s) and scanning is done on a clinical scanner. This is considered standard clinical care.

iv. If imaging study does require anything other than standard clinical care, this information must be included in detail in the study sheet.

c. Scheduling – Research Order Form obtained. Appointment scheduled and documented that appointment is associated with research including Grant #.

d. Storage in EeMR – follow EHC standards for inclusion in the EHC medical record for all non-sensitive studies.

e. Storage in PACS – follow EHC standards for inclusion in the EHC PACS system for all non-sensitive studies.

3. Research should be read by specific Radiology investigator and scanning is done on a clinical scanner.

a. Billing Process – utilizes ERMS billing processes for HQ and IDX
   i. PFS will set up $0 CPT codes to include in case details

b. Ordering Process – All research orders should be submitted via a scanned and faxed Research Imaging Order form indicating the specific Radiology investigator required.
   i. If imaging study does not require anything other than standard imaging protocol(s) and scanning is done on a clinical scanner. This is considered standard clinical care.
   ii. If imaging study does require anything other than standard clinical care, this information must be included in detail in the study sheet.

c. Scheduling – Research Order Form obtained. Appointment scheduled and documented that appointment is associated with research including Grant #.

d. Exam Completion - Tech will add Sticky Note to images in GE PACS to indicate reading should only be completed by specific Radiology Investigator.

e. Storage in EeMR – follows EHC standards for inclusion in the EHC medical record for all non-sensitive studies.

f. Storage in PACS – follows EHC standards for inclusion in the EHC PACS system for all non-sensitive studies.

4. Research subject undergoing imaging study relating to research trial on clinical scanner with no professional read requested. Radiology participation is for technical component only and scanning is done on a clinical scanner however, read is done off-site.

a. Billing Process – utilizes ERMS billing processes for HQ and IDX. Case set up in IDX for 7 day window.
   i. Some studies not being read by radiologist.

b. Ordering Process – All research orders will be submitted via a scanned and faxed Research Imaging Order form. Order form should indicate no professional read is required.
   i. If imaging study does not require anything other than standard imaging protocol(s) and scanning is done on a clinical scanner. This is considered standard clinical care.
   ii. If imaging study does require anything other than standard clinical care, this information must be included in detail in the study sheet.

c. Scheduling - Research Order Form obtained. Appointment scheduled and documented that appointment is associated with research including Grant #.

d. Exam Completion – Tech should assign the imaging study to the appropriate reading room coordinator and attach sticky notes if/when sent to PACS.

e. Radiology sign-off – Reading room coordinator should include a statement indicating the study was performed for research purposes only before signing off on the report.
f. Storage in EeMR – follows EHC standards for inclusion in the EHC medical record for all non-sensitive studies.
   i. Coordinator provides permanent research storage.

g. Storage in PACS – does not follow EHC standards for inclusion in the EHC PACS system, so images will not be stored in EHC PACs.

5. Research subject will undergo imaging studies performed on a clinical scanner, where the informed consent indicates nothing will go into the patient’s medical record or PACS.

   a. Billing Process – utilizes ERMS billing processes for HQ and IDX- Case is set up with 7 day window.
   b. Ordering Process – All research orders will be submitted via a scanned and faxed Research Imaging Order form.
      i. If imaging study does not require anything other than standard imaging protocol(s) and scanning is done on a clinical scanner. This is considered standard clinical care.
      ii. If imaging study does require anything other than standard clinical care, this information must be included in detail in the study sheet.
   c. Scheduling – Research Coordinator should contact the appropriate Imaging Department Supervisor to coordinate an appointment time. Supervisor should block room in Millennium scheduling. The research coordinator will coordinate the appointment time with the research subject.
   d. Exam Completion - After subject scanned, the technologist will:
      i. Provide images on an Emory approved CD for research coordinator.
      ii. Provide another CD for storage or send to research storage in VNA.
      iii. Delete study from clinical scanner to prevent possible delivery to PACS.

6. Research subject will undergo imaging study on research scanner with a professional read to follow.

   a. Billing Process- Utilize ERMS billing process for IDX (no technical billing). Case set up for 7 days in IDX.
   b. Ordering Process
      i. Scheduled, Ordered, Completed for date of exam by technologist.
      ii. If imaging study does not require anything other than standard imaging protocol(s) and scanning is done on a clinical scanner. This is considered standard clinical care.
      iii. If imaging study does require anything other than standard clinical care, this information must be included in detail in the study sheet.
   c. Scheduling- Scheduled, Ordered and Completed on date of scan by research scanner technologist.
      i. Research pricing for research scanners (Center for Systems Imaging at Wesley Woods) can be found at http://corelabs.emory.edu/csi/schedule/rates.html
   d. Storage in EeMR- Ordered under consult order. Radiologist dictates actual date of service.
   e. Storage in PACS- Requires review and approval by the PACS Oversight committee.

**RELATED DOCUMENT(S)/LINK(S):**

Research forms can be found at http://radiology.emory.edu/research/research-forms.html

For scans that use research rates, the rates can be found at http://www.ocr.emory.edu/ocr%20submission/research%20fees.html
Research pricing for research scanners (Center for Systems Imaging at Wesley Woods) can be found at http://corelabs.emory.edu/csi/schedule/rates.html

**DEFINITIONS:**

EHC - Emory HealthCare
CPOE - Computerized provider order entry
EeMR – Emory electronic Medical Records
RECIST - Response evaluation criteria in solid tumors
ERMS - Emory Research Management System
PACS - Picture Archiving Communication
HQ - Health Quest

Standard clinical care – Part of a medically indicated diagnostic process that a referring provider follows to manage a patient for a specified illness or clinical circumstance. In this case, standard clinical care includes all care and procedures associated with an imaging study that would ordinarily be received by patients not enrolled in a research study.

**KEY WORDS:**

Research
Imaging study
Clinical scanner
Clinical care
Billing
Ordering
Scheduling
Storage
ERMS

**REVIEW/APPROVAL SUMMARY:** Please select all Approving Bodies:

☐ EUH MEC  ☐ EUHM MEC  ☐ ESJH MEC  ☐ EJCH MEC  ☐ CNE Council  ☐ System Operations

**REVIEW/REVISION DATES:** 9/11/2018  |  **APPROVAL DATE:** 9/11/2018