



I. SCOPE

This SOP applies to all research studies that utilize Loyola Medicine Department of Radiology resources or personnel.

II. PROCEDURES

A. Utilization of Radiology services for research purposes follows the same procedures as utilization of Radiology services for clinical purposes.

1. Imaging for human subjects/patients must be ordered by a licensed provider.
 - a. Imaging to be billed to a research study must be ordered by a provider credentialed at Loyola.
 - b. The order is placed for the individual patient. "De-identified" scans are not permitted.
2. Imaging for human subjects/patients includes image acquisition and a professional read.
 - a. Images that have a professional read when performed for clinical care also require a professional read when performed for research purposes.
 - b. For this reason, imaging performed must at a minimum follow the protocol used for clinical care, i.e. be sufficient for diagnosis.
3. Imaging is scheduled in advance.
 - a. Human subjects/patients are scheduled in Epic under their true identity.
 - b. If the protocol requires the same technologist or the same equipment to be used for each study-related scan, the study team should notify Radiology in advance and expect to schedule scans 4 weeks prior to the date of service.
 - c. Non-human scans are scheduled with the modality manager at least 2 weeks in advance of the requested scan date.
 - (1) Non-human scans should expect to be scheduled outside of normal business hours.
 - (2) The 2 week notification period allows sufficient time to schedule a technologist to be present.

B. Software or hardware modification to Radiology equipment requires prior approval as described in SOP Operational and Financial Assessment of Research, SOP Management of Research Equipment in LUMC, and LUMC policy Institutional Approval of Clinical Research.

C. Research studies are expected to cover the costs of utilization of Radiology services and resources.

1. The prices for patient care services are determined according to LUMC policy Pricing Structure for Clinical Research and are available in the Research Channel.
2. The prices for non-patient care services are available in the Research Fee Schedule-Radiology.
3. Researchers are to provide the information necessary for invoicing the study at the time Radiology services are requested. See SOP Invoicing for Research Non-Patient Care Costs.

D. This SOP may be extended to requests for Radiology services for product testing, quality, and/or educational purposes.

E. Any exceptions to this SOP require approval from Radiology leadership. Approvals are facilitated by submitting a request to LUMC Clinical Research.

III. REFERENCES

- A. SOP PRO-003 LUMC Operational and Financial Assessment of Research
- B. SOP PRO-005 Management of Research Equipment in LUMC
- C. LUMC Policy CR-002 Institutional Approval of Clinical Research



- D. LUMC Policy CR-001 Pricing Structure for Clinical Research
- E. SOP FIN-009 Invoicing for Research Non-Patient Care Costs

IV. ASSOCIATED DOCUMENTS AND FORMS

- A. Research Fee Schedule- Radiology

V. APPROVALS

Regional Chief Clinical Officer (or designee)

11/2/21

Date