Stanley Manne Children's Research Institute™

Ann & Robert H. Lurie Children's Hospital of Chicago®

Research Rates, Fees & Included Services

This schedule describes the fixed fees and patient care costs associated with Ann & Robert H. Lurie Children's Hospital of Chicago participation in clinical research studies. The fees are set by the hospital service areas providing the associated services, are considered non-negotiable, and are subject to annual changes. The charges are only incurred when the specified service is required by the study (e.g., if no investigational drug is required, IDS Pharmacy charges do not apply).

F&A Rate

Our Indirect Cost Policy defines the rates applicable to externally sponsored projects. Our Facilities and Administrative (F&A, indirect cost or overhead) rates may apply to items in the per patient pricing as applicable per funding source. The administrative prices within this schedule are our total costs and include our F&A rate as applicable.

Fixed Start-up, Maintenance & Close-out Costs

Institutional Review Board (IRB)/ Research Compliance Oversight	
Administrative	
• These fees apply to all non-federal, externally funded studies whether reviewed by the Lurie Children's IRB or when relying on an external IRB • Fees applied at time of initial review/reliance, periodic review (typically annual), and any amendments to protocols and/or informed consent documents • These prices do not include IRB fees from a third party, such as the Western Institutional Review Board (WIRB)	**Initial Review/Start-up:** $3,000 **Periodic Review:** $1,000 **Protocol and/or Consent Form Amendment:** $1,000

Clinical Research Billing Compliance	
Administrative	
• Review of study protocol, budget, contract, and consents to develop a compliant billing grid and study budget following applicable billing regulations • Negotiate initial budget and amendments with Sponsors	**Start-up:** Industry Sponsored: $4,500 **Amendment:** Industry Sponsored: $1,000

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Clinical Research Unit (CRU)	
Administrative	
• Fee applied at study start-up offsets costs associated with processing, reviewing, and approving submissions to the CRU • Clinical research funded by Federal, Foundation and Department/ Divisions will not incur this fee	**Start-up:** Industry Sponsored: $3,000
Per Patient	
• Skilled nursing, tiered visit charges based on visit complexity, billed through Epic • Room Charges • Assessments, including but not limited to vital signs, height, and weight • Specimen collection (i.e. blood draw, urine collection) • Medication administration including observation and required intervention • PIV Insertion for PK/PD collection at multiple time points of the protocol • CRU Nurse Procedures (including but not limited to ECG, PFT, sweat test, etc.) • Additional tasks not noted above but requiring RN support	Industry Sponsored: Tiered system based on time and visit complexity, ranging from $50-$130 per 30 minutes Federally Sponsored or PI Initiated: Tiered system based on time and visit complexity, ranging from $11.16-$83.70 per 30 minutes

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Investigational Drug Service (IDS) Pharmacy		
Administrative		
Start-up: • Fee applied at start-up, includes initial review of protocol and IDS Pharmacy Letter of Support process, initial meeting with study team prior to participant recruitment, development of procedures for IDS Pharmacy staff, development of SOP for inpatient pharmacy staff, Site initiation visit, study set-up in Vestigo (electronic drug accountability system), working with pharmacy informatics for Epic medication entries (e.g. eRXs, beacon treatment plan), initial training of IDS pharmacy staff Annual Maintenance: • Storage of medication, daily monitoring of room, refrigerator, and freezer temperatures, monthly audits - Inventory of study medication, expiration inspections of study medication, updated IDS Pharmacy staff training with new study documents, study monitor visit set-up Close-out: • Final inventory reconciliation of medication, review all documents for proper signatures, dates, etc., close-out visit with study monitor - provide copies of requested documents including but not limited to shipping documents, accountability log, training logs; destroy remaining medications on-site or return to sponsor by monitor, prepare pharmacy paperwork for long term storage, close-out procedures - inform pharmacy informatics & CRU regarding retirement of eRX, billing for study, removal of IWRS access, print out drug accountability record, Vestigo update Exemption Storage: • Approval must be obtained by the IDS pharmacy. All other studies will follow the IDS Drug Destruction Criteria (please contact IDS Pharmacy for details)		**Start-up:** Industry Sponsored: $3,000 Federally Funded/PI Initiated: $1,000 **Annual Maintenance:** Industry Sponsored: $1,000 Federally Funded/PI Initiated: $150 **Close-out:** Industry Sponsored: $250 Federally Funded/PI Initiated: $150 **Annual Exemption Storage:** Industry Sponsored: $1,000
Per Patient		
Preparation & Dispensing (cost per preparation)	Oral, topical, or inhaled medication prescription	Industry Sponsored: $50 Federally Funded/PI Initiated: $35
	Straight injection	Industry Sponsored: $75 Federally Funded/PI Initiated: $50

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	IV admixture	Industry Sponsored: $110 Federally Funded/PI Initiated: $75
	Complex IV admixture (medication needing special handling and disposal processes and include studies in which Institutional Biosafety Committee approval is required)	Industry Sponsored: $225 Federally Funded/PI Initiated: $100

Research Laboratory	
Administrative	
• Fee applied at start-up, covers the cost of pathology and lab analyzing the protocol and the applicable lab manuals to determine the requirements for blood, urine, or tissue submission, the necessary supplies to meet the requirements, and the creation of study-specific requisition forms	**Start-up:** Industry Sponsored: $750 Non-Federal/ Non-Industry: $500
Per Patient	
• These fees include the costs associated with implementing study-specific processing based on complexity, storage, and shipping procedures	In-house lab tests, & phlebotomy fees- see Lab Panel List within Research Charge Master/Fee Schedule Processing Charges: Tiered system based on time and complexity, ranging from $5-$195

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Medical Imaging	
Administrative	
Start-Up: • Fee applied at start-up, this fee offsets costs associated with processing, reviewing, and approving submissions to Medical Imaging. This includes analyzing the protocol and applicable medical imaging manuals to determine requirements for scans and the necessary equipment to meet the requirements • Clinical research funded by Federal, Foundation and Department/ Divisions will not incur these fees.	**Start-up:** Industry Sponsored: Tier 1 Simple: $1,000 Tier 2 Moderate: $2,000 Tier 3 Complex: $3,000
Amendment Fee: • Fee applied upon new support agreement provided to the study team. This fee offsets the cost of reviewing and approving updated study documents and modifying the current study support plan	**Amendment:** Industry Sponsored: $750
Specialty Support Services: These fees include the costs associated with implementing study-specific protocols and are applied throughout the life of the study as dictated by the protocol.	**Specialty Support Services:**
• Imaging Protocol Build: Fee associated with creating custom acquisition, analyses or data-manipulation, protocol optimization that may be non-standard and time-intensive, and/or study-related analysis software or oversight of minor equipment installation	Imaging Protocol Build: $630 per scanner
• Technologist Training: This fee is associated with industry sponsored studies that require training of Medical Imaging personnel for study initiation. This can be completed by quiz, webinar, or on-site training. Charges are based on modality and category of training	Technologist Training**:** $90 per technologist/hour
• Research Analysis Report: Provides additional information regarding a research-related scan that is required for the research study or clinical trial but is not normally found in a standard radiologist report. This might include specialized interpretation requirements, measurements, as well as consistent comparisons between baseline and follow-up scans	Research Analysis Report: Basic Interpretation: $100 per body part scanned Complex Interpretation: $200 per body part scanned
• Phantom Scan:	Phantom Scan: $590 per scan

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Some studies require phantom scans that must be performed for QA/QC purposes before a study is activated or continuously throughout the study cycle. • Raw Data/QA/QC Collection: Some studies have additional requirements related to raw data/ QA/QC copying. Estimates will be provided at study start-up depending on study needs. • Volunteer Scan: some studies require healthy volunteer scans that must be performed for QA/QC purposes before a study is activated.	Raw Data/QA/QC Collection: $300 per scan Volunteer Scan: Per procedures performed, per charge master
Per Patient	
• Hospital and professional charges for procedures performed are charged based on the research fee schedule and outlined during the letter of support process with this service area	Per Procedures Performed

Cardiopulmonary Lab	
Administrative	
• Research specific assessments within protocols which may require significant time and effort for training and completion of assessments from Cardiopulmonary Lab staff will be outlined within the letter of support process and invoiced as applicable	**Start-up:** Invoiced based on protocol complexity **Amendment:** Invoiced based on protocol complexity
Per Patient	
• Hospital and professional charges for procedures performed are charged based on the research fee schedule and outlined during the letter of support process with this service area	Per Procedures Performed