Investigational Drug Service Fees for Fiscal Year 2024 Effective 9/1/23

To bring into alignment the Investigational Drug Service fee structure for Lucile Packard Children's Hospital Stanford with Stanford Health Care, the following will be applied to all drug trials. Exemption to the new fee structure will be applied to Investigational drug trials that have previously received a quote.

- Set-up Fee \$2,780 (one-time charge)
 - Pharmacist Involvement in Protocol Development Additional \$4,120 (Median time spent: 40 hours)
 - Treatment Plan and/or Road Map Validation Additional \$515
- Annual Maintenance Fee \$2060 per year (starting 1 year from date of receipt of IP) Includes: Shipping and receiving of supplies & medications, monitoring fees, closure fees, IP documentation, etc.
 Maintenance of Controlled Substances and/or Refrigerated/Frozen Medications - Additional \$1,545
- - Dispensing Fee (per dose per drug)
 - Oral Medications/Single Injections:
 \$155 per dispensation
 - o Intravenous Infusions/Chemotherapy(oral & IV)/Viral Vector Gene: \$260 per dispensation
 - Home Durable Medical Equipment (Pumps and Accessories): \$105 per dispensation
- Electronic Data Capture (EDC)
 - Up to \$410 per month, depending on complexity and enrollment volume.
 - Applies only to EDC into sponsor's server based programs.
 - Registering shipment consignment receipts into IXRS is not considered EDC.
 - Logging into IXRS to review dispensing information is not considered EDC.
- Drug/Supply Procurement
 - Procurement and Handling of Medications/Supplies: Drug/Supply Acquisition Cost + 23% surcharge

All quoted fees are subject to change. Adjustments may be made on an annual or more frequent basis. This may be due to updates to study design, necessitating changes to pharmacy participation requirements. Commercially available drugs used for investigational trials that are not provided by the sponsor / study group / investigator may be purchased thru the LPCH Department of Pharmacy at adjusted acquisition cost. The new fee structure has been approved by Executive Director of Pharmacy. Request for an exemption to the standard investigational drug trial fees may be discussed with the Executive Director of Pharmacy and the Clinical Research Support Office.



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