July 1, 2019

To Whom It May Concern:

Please see the justifications for the fees on our fee schedule. All fees include but are not limited to the procedures and tasks listed.

The KCPCRU Administrative Start-Up Fee covers:

❖ Pre-selection Process:
  - Site information questionnaires
  - CDA
  - Preliminary review of protocol by PI, sub-investigator(s), Leadership Nurse Coordinator and Regulatory Staff
  - Feasibility analysis including determination of patient population, staffing, expertise, etc.
  - Pre-site visit
  - Determine study specific training required for EDC, IWRS/IVRS etc.

❖ After site selection:
  ❖ Completion of the following:
    - Financial Disclosure Agreement for PI and sub-investigators
    - FDA 1572
    - Protocol Review Acknowledgement signature
    - Investigator Brochure Acknowledgement signature
    - Curriculum Vitae and Medical Licenses for PI, sub-investigators and Key Personnel
    - Any other documents required by the Sponsor or their CRO’s
    - Local Laboratory Certifications,
    - Local Laboratory Normal Ranges
    - CV of Lab Director
    - IRB Assurance and Membership List
  ❖ Develop Study Plan for implementation and completion including:
    - Recruitment/screening/enrollment
    - Study supplies
  ❖ IRB submission of all required documents:
    - Preparation of Scientific Review Form
    - Preparation of site informed consent/HIPAA, assent and Revocation
    - Time for sponsor/site language negotiations
    - Preparation of partial waiver
    - Preparation of all advertisements and patient materials
    - Invoice for IRB fee
    - Completion of the IRB electronic submission and revision based on IRB modifications requested
    - Obtaining required information from sponsor for electronic submission such as information on CRO, contact information, IND, clinicaltrials.gov, etc.
    - Obtaining all of the required electronic signatures by study site personnel
    - Documentation of all required IRB training
  ❖ Preparation and submission of all documents and information to the Norton Healthcare Office of Research Administration (NHORA)
  ❖ Submission of IRB Approval Notices and Acknowledgements to the Sponsor
  ❖ Submission of NHORA Approval Notices and Acknowledgements to the Sponsor
  ❖ Preparation and submission of all contract information to the Department of Pediatrics and the Office of Industry Contracts (requires 3 sets of forms for internal review):
    - Obtain required signature of all study personnel, Division Chiefs and Department Chairman
  ❖ Clinical Budget preparation
    - Review of budget and completion of internal budget forms
    - Pharmacy and Lab Fee requests from NHORA
• Time for site negotiations with the sponsor
  • Finalization of budget
  • Completion/submission of Site Contact Information

The KCPCRU Annual Fee:
  • Monitoring requirements for the year
  • Financial activities required for the conduct of the study on a monthly basis not including budget or contract amendments
  • Regulatory maintenance for the conduct of the study on a monthly basis not including amendment submissions
  • Clinical maintenance for the conduct of the study not specifically related to subject care.
  • Internal quarterly review of study performance and feasibility.
  • IRB submission of the Continuing Annual Review which includes making document modification (such as ICF/ASSENT, etc.), obtaining, scanning and redacting the last 5 subject's ICFs, sponsor monitoring visit letters and submitting them to the sponsor, PI, research personnel once IRB approval is received for the changes to all staff.
  • Review and processing of all IND safety reports.

The KCPCRU Regulatory Amendment Fee:
  • Any sponsor initiated amendment, i.e. protocol, IB, administrative letters, patient materials, ICF, etc. covers the following:
    ➢ Task: Receipt of the documents, processing and making document modification (such as ICF/ASSENT, etc.), language negotiations with sponsor, electronic submission application, downloading approval documents and submitting them to the sponsor, PI, research personnel, training and documentation of training for the changes to all staff.

The KCPCRU Financial Amendment Fee:
  • Any sponsor initiated budget and contract amendments
    ➢ Task: Receipt of the documents, completion of the required internal processes for contract amending, negotiations on any budget changes with the sponsor, acquiring any outside (of the KCPCRU) pricing processing, revision of database budget, billing templates, etc.

The KCPCRU Remote Monitoring Fee:
  • The set fee (inclusive of indirects) for remote monitoring for Kosair Charities Pediatric Clinical Research Unit is: 1) $500.50 (0-1 subjects being reviewed) and 2) $877.50 (2-5 subjects being reviewed). This fee includes the time and preparation of clinical research and regulatory documents to be provided to the monitor, as well as time required by the monitor of the PI, clinical team, and regulatory team for any questions/clarifications.

  Additionally, per our site SOP all IRB approvals, CVs, licenses, 1572s, signature pages, sponsor and regulatory documents/communications, etc. are sent to the sponsor in real time and saved in the regulatory file. Regulatory obligations, during remote monitoring, places the burden of confirmation, which are normally confirmed by a CRO (during on-site monitoring visits) back on the local staff. Clinical research staff are frequently required to be available for questions during remote monitoring which consumes their time.

The KCPCRU Prescreen Fee:
  • Data analysis and review of the internal medical records, outpatient clinic medical records, service scheduling for those related to study treatment, KCPCRU database query for subjects that may be eligible for approach on a quarterly schedule. This fee is to be paid regardless of enrollment.

The KCPCRU Close-out Fee
  • The close-out fee includes but is not limited to the following actions: completing the appropriate documentation for end of study as well as the IRB submission, account close-out, and close-out Visit.

The KCPCRU Archiving Fee:
  • The preparation of all study materials organized and cataloged according to University of Louisville Archiving Requirements, Pick-up of record and long term storage.
The KCPCRU Pharmacy Set Up Fee:
- The set-up of the pharmacy to conduct the study. This includes preparing the appropriate documentation for drug receipt, storage, and accountability. It also includes the time required by the pharmacist for specific requirements of the sponsor training for drug and accountability systems training.

The KCPCRU Pharmacy Annual Fee:
- These procedures are done per study throughout the conduct of the trial: IWRS; Receipt Accountability; Store received drug; Maintain current IB and protocol; Maintain communications; Temperature monitoring review; Address temperature excursions; Maintain expiration log for drug; Monitor visits; Drug Return and destruction during study, etc.

The KCPCRU Pharmacy Close-Out Fee:
- This includes completing the appropriate documentation for end of study as well as the disposal or return of investigational product to the sponsor at the conclusion of the study. It also includes the time required by the pharmacist for the close out visit and other specific requirements of the sponsor.

The KCPCRU FDA or sponsor audit Fee:
- The sponsor covers costs related to an FDA or sponsor audit. This is a per-day fee and the amount invoiced will be based on the time spent to complete the audit.

Respectfully,

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