

Payee Name: KUMC Research Institute, Inc.
Not For Profit 501(c) (3)

Payee Address: University of Kansas Medical Center
Research Institute, Inc., MS 1039
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Executive Director, Research Institute

Mail Contracts to: Molly Gunter, MS, CCRP
Director, Clinical Research Administration

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University/Institution Federal I.D.: #48-1108830

Clinical Trial Budget:

Please include the following upfront, non-refundable one time fees on Industry Sponsored budgets:

- § IRB submission/review fee: \$2500
- § IRB recertification fee: \$1500 per recertification
- § Amendment fee: \$1200 per IRB full board amendment
- § KUSM-Wichita IRB one time administrative fee: \$1000
- § Research Institute Administrative fee: \$2500
- § Pharmacy Opening/Closing Fee (when applicable): is attached on a separate sheet
- § Archival Storage fee (when applicable): approx \$560 plus overhead
- § Principal Investigator hours: \$200 per hour (exceptions may apply)
- § Study Coordinator hours: \$75 per hour
- § Audit fee (regardless of cause): \$1,000 per day for Sponsor generated audits/ \$2,000 per day for FDA generated audits

\$5000 is a non refundable Investigator administrative fee which includes, but is not limited to:

- § start up costs for time spent by the PI and other staff
- § database training
- § regulatory documentation preparation, consent form review, fax, mail
- § monitoring visits
- § continued maintenance of site regulatory and subject binders
- § initial investigator/staff training, continuing training, web training sessions
- § protocol/database/web training for additional study personnel after initiation
- § use of equipment
- § conducting site selection & site initiation visits
- § resources and space for monitoring visits
- § review and ordering preparations for drug, lab and equipment inventory
- § recruitment efforts
- § Ongoing regulatory/IRB requirements/processing (ie RCRTs, SAEs, revised 1572s etc)

NOTE: Other Administrative fees may apply

Facilities and Administration (F&A) Rate

Privately funded F&A: 33%

Federal F & A: All other research and sponsored programs will be assessed at the current federally negotiated rate in effect at the time of award acceptance.

Fee Definitions:

- § **Research Institute Administrative fee:**** The fee includes complete administrative study set-up, regulatory document collection and filing, study communications, budget preparation, and contract review.
- § **IRB fee:**** This fee includes protocol review by the Clinical Research Administration Division, consent form preparation, University of Kansas Medical Center (KUMC)/Western (WIRB) IRB submission and funding for education/training opportunities for IRB members and administrative expenses for the IRB office.
- § **Principal Investigator Hours:**** Protocol review, study subject review, time spent with study subjects for obtaining consent and study-related activities, meetings, phone calls.
- § **Study Coordinator Hours:**** Study set-up, subject review, time spent with study subjects for obtaining consent and study-related activities, meetings, site and monitoring visits, protocol, education, case report form completion, travel to investigator meetings and other study-related activities.

*** Administrative fees, IRB fees, Principal Investigator and Study Coordinator hours are still payable even if the study does not proceed at KUMC i.e. is cancelled or withdrawn.*

The Research Institute is the contracting and fiscal entity for privately sponsored research at The University of Kansas Medical Center. The Clinical Research Administration Division of the Research Institute is a central office that assists investigators with consent form preparation, IRB submission, regulatory documents, budgets and contract review. For initial questions, please direct to Molly Gunter, MS, CCRP Division Director at 913-588-5969.

Revised 7/1/11

Investigational Drug Services (IDS) Fee Schedule - July 2011

Set-up Fee	\$700* one-time fee	
Dispensing Fee: IV drug	\$30 per dose	<i>time involved < 15 minutes</i>
	\$50 per dose (standard)	<i>time involved 15-30 minutes</i>
	\$75 per dose	<i>time involved > 30 minutes</i>
Dispensing Fee: Oral drug	\$15 per drug dispensed	<i>Standard, when no further compounding is involved</i>
Dispensing Fee: Chemotherapy	\$150 per dose (standard)	<i>Standard</i>
	\$200 per dose	<i>Lengthened or complex preparation process**</i>
Medication Acquisition	Fee dependent upon materials/supplies acquired by IDS in such instances where sponsor does not supply	
Monitoring Visit Fee	\$50 per visit for each visit beyond four/year	
After-hours fee	\$100/instance	
Storage Fee	\$100/year each year study remains open with no patients enrolled***	
Close-out Fee	\$250 one-time fee	

* A \$700 set-up fee assumes a study of moderate complexity, based on IDS staff determination; this fee may be increased to \$900 for a high complexity study or decreased to \$500 for a low complexity study

** A lengthened or complex chemotherapy preparation process involves preparation time > 30 minutes, handling of any gene therapy product, or any other such procedures that exceed standard chemotherapy preparation based on IDS staff determination

*** Fee includes relabeling, inventory, expiration date monitoring, protocol amendments and other ongoing study procedures that are necessary regardless of subject enrollment

Definitions:

After-hours Fee – Includes IDS on-site involvement between the hours of 6pm-8am for the purposes of randomization, dispensing (if necessary), monitoring labs/drug levels, or other such required procedures that cannot take place during normal working hours.

Close-out Fee – Includes everything involved in the close-out of the study, including attendance at the Close-out Visit, final disposition of drug along with required paperwork, and preparation for long-term storage and associated fees with such storage.

Dispensing Fee – Includes all work that goes into the preparation of the finished product; this may include, but is not limited to, IVRS/IWRS involvement, required paperwork, accountability, aseptic procedures involved in IV preparation, and labeling. For chemotherapy studies this fee also covers cytotoxic handling and ongoing disposal.

Set-up Fee – Includes everything involved in the start-up of the study, including familiarization with the protocol, pharmacy manuals and other study materials, attendance at the Site Initiation Visit, training of pertinent staff, acquisition of additional study materials not supplied, and development of investigational procedures/materials, such as database entries or nursing training documents. For chemotherapy studies, this fee also covers protocol build and maintenance in Beacon, the oncology module in O2.