

RESEARCH PHARMACY SERVICE FEE ESTIMATE FOR CLINICAL TRIALS

DATE:

STUDY TITLE:

PROTOCOL NUMBER:

R.E.B. NUMBER:

QUALIFIED
INVESTIGATOR:

I. ADMINISTRATIVE FEES

a)	<i>Initiation Fee</i>	<i>Industry</i>	\$ 3000.00
		<i>Investigator Initiated</i>	\$ 1500.00

- Review of protocol and pharmacy binder to assess level of Pharmacy involvement
- Review of Clinical Study Request Tool for accuracy
- Pre-initiation and initiation meetings with investigator, study coordinator and study monitor
- Preparation of drug dispensing procedures
- Preparation of drug and patient accountability forms
- Preparation of pre-printed prescriptions
- Preparation of dispensing labels
- Register individual technicians and pharmacists with IVRS and compile necessary documents required by sponsor prior to start of trial
- Communication with study monitor and research staff to clarify drug preparation, dispensing and documentation procedures
- Communication and training of dispensing procedures to staff
- Procurement and storage of initial drug supplies

b)	<i>Maintenance Fee</i>	<i>(\$600.00/ year, charged at \$50.00/month)</i>	
	=	\$50.00/month x # projected months	\$

- Monitoring of refrigerator and room temperatures
- Monthly billing statement preparation
- Retrieve patient study medication returns from the Study Coordinator; document and store
- Study Monitor visits: meet with monitor, clarify and/or resolve any issues from monitor visits, dispose of, or package used patient medication for return to sponsor
- Review alerts, newsletters, updates and new directives received from the sponsor during the course of the trial
- Update procedures as needed and file correspondence documents
- Clarification and/or resolution of issues arising during the course of the trial
- Replace and return (or re-label) expired clinical drug supplies during the study
- Maintain inventory records and re-order supply as needed

c)	Receipt of Drug Shipment (\$25/shipment after initial shipment)	\$
	= \$25.00/receipt x # projected shipments per year x # years	
	<ul style="list-style-type: none"> • Receive, unpack and stock drug supplies • Update drug accountability logs • Read/process and return temperature recording device to sponsor, if required • Register receipt of clinical trial materials with IVRS/IWRS • Fax packing slips to confirm receipt of drug supplies • Mail packing slips to confirm receipt of drug supplies 	
d)	Study Closeout	\$ 500.00
	<ul style="list-style-type: none"> • Reconcile final drug accountability with or without study monitor • Return or destruction of drug supplies to sponsor at conclusion of study • Preparation and storage of pharmacy related study documentation for 25 years 	
e)	Protocol Amendments	\$
	<ul style="list-style-type: none"> • Any amendment to protocol which requires revision to Pharmacy procedures \$100-\$200 per episode 	

II. **DISTRIBUTION FEES**

a)	Oral Doses	
	<ul style="list-style-type: none"> • IVRS calls for drug assignment or patient randomization • Materials: printing of patient profiles, prescription labels, vials • Dispensing of study drug • Updating of Patient and Drug Accountability Logs and other sponsor-required documentation 	
	Dispensing fee (@\$15.00/prescription)	
	= \$15.00/Rxn x #drug items/patient x # patients	\$
b)	Aseptic Preparations	
	<ul style="list-style-type: none"> • IVRS calls for drug assignment or patient randomization • Materials: I.V. bags/evacuated bottles, transfer sets, needles, syringes Filters, swabs, ziplock bags, UVLI bags, labels • Preparation of study drug • Updating of Patient and Drug Accountability Logs and other sponsor-required documentation 	
	Simple dilution IV solutions or syringes (@\$25.00/bag or syringe)	
	= \$25.00/bag or syringe x # of bags/syringes x # patients	\$
	Simple reconstitution and dilution IV solutions or syringes (@\$30.00/bag or syringe)	
	= \$30.00/bag or syringe x # of bags/syringes x # patients	\$
	Complicated and chemotherapy IV solutions or syringes – more than 20 minutes preparation time(@\$75.00/bag or syringe)	
	= \$75.00/bag or syringe x # of bags/syringes x # patients	\$
c)	Packaging, Batching and Extemporaneous Mixtures	\$
	= \$55.00/hour x # of hours	
d)	Supplies	\$
	Cost of Drug or Supplies (if purchased by Pharmacy)	
	IV solutions, syringes, tubing, filters and medication that is not supplied by sponsor	\$

III. ON CALL SERVICES

a)	Pharmacist Stand-By	(\$4800.00/ year, charged at \$400.00/month)	
	• Pharmacist to carry a pager and be available to prepare drug outside of regular Research Pharmacy hours		
=	\$400.00/month x # projected months		\$
b)	Pharmacist Call Back	(\$330.00/ call back)	
	• Preparation of drug outside of regular Research Pharmacy hours		
=	\$330.00/call back x # projected call backs		\$

TOTAL RESEARCH PHARMACY SERVICE FEE ESTIMATE: \$

Payment Terms:

- All study charges will be deducted from the study account by the Office of Research Administration. Pharmacy will send the Qualified Investigator a monthly statement (or as charges occur) for their record.
- The initiation fee will be charged at pharmacy study initiation. In the event that the trial does not receive REB approval, only the Pre-REB fee will be charged).
- The Maintenance fee will be charged on a monthly basis until the pharmacy study close-out visit has occurred.
- The Pharmacist Stand By fees will be charged on a monthly basis until written notification that this service is no longer required.
- All other fees will be charged on a monthly basis, as services occur.
- All Pharmacy fees are estimates only and are subject to change, based on actual workload and cost incurred.
- All Pharmacy fees are subject to increase, with notice, based on direct cost escalations.