

Subject: <b>FEE STRUCTURE</b>		Issued By: <b>ADMINISTRATION</b>	
		Approved By: Kathleen R. Hurtado President & CEO	
Policy #: 1004	Issue Date: June 15, 2006	Revised Date: October 15, 2007	Effective Date: October 1, 2007

**PURPOSE**

To clarify and publish HRA's Fee Structure relative to Industry-Sponsored clinical trials.

**POLICY**

HRA will charge the following fees, when applicable, for all of the Industry-Sponsored clinical trials we administer:

Investigational Drug Service (IDS) Pharmacy Fees		
Pharmacy Fixed	Per Protocol Except for <b>Annual</b>	Fee
	Pharmacy Setup Fee	\$1,000.00
	<b>Annual</b> Storage & Maintenance and Auditor/Monitor Visits	\$1,000.00
	Termination (Close-Out) of Study	\$500.00
Dispensing - Variable Fee	Per Dose Except for <b>Hourly</b>	Fee
	IV Infusion (normal hours)	\$65.00
	IV Infusion (off hours)	\$97.50
	Oral Dose (normal hours)	\$30.00
	Oral Dose (off hours)	\$45.00
	Bolus Injection (normal hours)	\$45.00
	Bolus Injection (off hours)	\$67.50
	<b>Hourly</b> Compounding Fee	\$75.00
Other Fees - Variable Fee	Per Research Participant/Call/Visit or <b>Monthly</b>	Fee
	Randomization per Research Partic.	\$90.00
	<b>Monthly</b> Used Vial Storage Fee	\$100.00

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HRA Fee Structure, Continued...		
<b>Labor</b>		
Fixed - Either Actual or Market Rates, Whichever Is Higher. The Hourly Rates Listed Here Do NOT Contain Fringe of 32%	Rate Per Hour	Fee
	PI	\$120.00
	Nurse/Coordinator	\$42.50
	Data Manager	\$27.00
	Admin	\$15.00
<b>Administrative Start-Up Costs</b>		
Non-Refundable Start-Up Costs	Per Protocol Except for <b>Re-consent</b>	Fee
	IRB Preparation	\$1,500.00 <sup>1</sup>
	IRB Submission/Review	\$2,000.00 <sup>2</sup>
	Annual IRB Renewal	\$800.00
	Protocol Amendment Fee	\$1,000.00 <sup>3</sup>
	<b>Per Participant Re-consent</b> Fee	\$50.00 <sup>4</sup>
	Spanish Translation	\$500.00
	CISO Fee <i>Oncology Trials Only</i>	\$5,000.00
<b>Other Fees</b>		
Other Fees	Per Year / Per Submission	Fee
	Record Retention per Year	\$100.00
	Excessive SAE Submissions per SAE	\$25.00

<sup>1</sup> **IRB Prep Fees** are split between the project and HRA based upon the relative effort put forth by each entity relative to IRB submission preparation.

<sup>2</sup> **IRB Submission Fee** The entire \$2,000 IRB Submission Fee goes to the IRB.

<sup>3</sup> **Protocol Amendment Fee** will be split 50%-50% between the project and the IRB. Note that the \$1,000.00 amendment fee only applies to protocols requiring "Full-Board approval." There is no charge for an amendment to an "expedited review" protocol.

<sup>4</sup> **Re-consent Fee** this fee will go 100% to the project.

### **BOARD APPROVAL OF SIGNIFICANT CHANGES**

HRA's Board of Directors must approve SIGNIFICANT changes to this Fee Structure Policy. However, minor changes to these fees (equal to or less than \$1,000 per project) – including

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adding descriptions for the purpose of clarification, and/or shifting fees from one line item to another – may be done at the discretion of HRA’s President & CEO without Board approval.

**RESPONSIBILITY**

- HRA Executive Management
- HRA Board of Directors
- HRA Office of Contract Administration
- HRA Finance Department