

# UNIVERSITY OF LOUISVILLE. CTU

## CLINICAL TRIALS UNIT

**Memorandum: Clinical Trial Fee Structure**

**Effective Date: 01/02/2018**

The following lists contain items and processes that may be completed to ensure compliance with the rules and regulations that govern clinical research. The below fees will be charged to the study account established for the protocol and shall be covered by the organization that is sponsoring or funding the clinical research. A stand-alone letter for fee justification will be provided upon request.

	<i>Procedure</i>	<i>Description</i>	<i>Total</i>	
1	Administrative Start-up	<i>A one-time non-refundable fee</i>	\$11,277.00	
2	CTMS Set-Up	<i>A one-time non-refundable fee, if applicable</i>	\$1,500.00	
3	Administrative Annual	<i>An annual non-refundable fee</i>	\$2,835.00	
4	Amendment	<i>A non-refundable fee charged for each sponsor required IRB amendment and sponsor prompted budget or contract.</i>	<i>Regulatory</i>	\$428.40
			<i>Financial</i>	\$378.00
5	Pre-Screening	<i>A non-refundable quarterly fee, if applicable</i>	<i>Outpatient</i>	\$907.20
			<i>Inpatient</i>	\$2,419.20
6	Training	<i>Required additional protocol training for all personnel on DOA or 1572 through a Sponsor system</i>	<i>Study personnel</i>	\$50.40/hour
			<i>MD/PhD/PharmD</i>	\$189.00/hour
7	Sponsor/FDA Audit	<i>Per Day Fee</i>	\$541.80	
8	Local SAE reporting	<i>Per hour Fee</i>	\$75	
9	Administrative Close-Out	<i>A one-time non-refundable fee</i>	\$2,299.50	
10	Archiving	<i>A one time non-refundable fee</i>	\$1,071.00	
11	Study Drug Storage and Accountability	<i>A one-time non-refundable fee. This applies only if the study drug is stored in the unit.</i>	<i>Ambient</i>	\$1,039.50
			<i>Refrigerated</i>	\$1,512.00
12	Pharmacy (Pediatric only)	<i>An annual non-refundable fee. This applies only if the study drug is stored in the unit's satellite pharmacy</i>	<i>Simple</i>	\$4,252.50
			<i>Complex</i>	\$4,866.75
13	Pharmacy close-out (Pediatric only)	<i>A one-time non-refundable fee. This applies only if the study drug is stored in the unit's satellite pharmacy</i>	\$756	

**\*\* IRB & hospital facility fees are separate from the fee schedule above \*\***

Sincerely,

Craig McClain, MD  
 Associate Vice President for Health Affairs/Research  
 Associate Vice President for Translational Research  
 Director of the UofL Clinical and Translational Sciences Institute

Lale Akca, MBA, CCRA  
 Executive Director  
 University of Louisville  
 Clinical Trials Unit