

Norton Children's Research Institute
Fee Schedule - Level 3

Procedure	Description	Subtotal	30% OH	Total	
Administrative Start-up Fee	<i>This is a one time non-negotiable and non-refundable fee. If the sponsor pulls the study before start-up process is completed, they are responsible to cover the costs for the work completed on the project. A stand alone letter provided for fee justification.</i>	\$14,701	\$ 4,410.32	\$ 19,111.37	
MCA Fee	<i>This is a one time non-negotiable and non-refundable fee. If the sponsor pulls the study before start-up process is completed, they are responsible to cover the costs for the MCA development if this task has been completed.</i>	\$2,138	\$ 641.40	\$ 2,779.40	
Administrative Annual Fee	<i>This is an annual non-refundable fee. A stand alone Letter provided for fee justification.</i>	\$3,782	\$ 1,134.48	\$ 4,916.08	
Amendment Fee	<i>This is a non-refundable fee charged for each sponsor required IRB amendment and sponsor prompted Budget or Contract. A stand alone letter provided for fee justification.</i>	\$738	\$ 221.43	\$ 959.53	
Pre-Screening Fee	<i>This is a non-refundable quarterly fee and only requested if applicable to the study. A stand alone letter provided for fee justification.</i>	Outpatient	\$792	\$ 237.60	\$ 1,029.60
		Inpatient	\$2,112	\$ 633.48	\$ 2,745.08
Training Fees for Sponsor Specific Protocol System	<i>This fee is charged for studies in which the sponsor requires additional protocol, regulatory or financial systems training for all personnel on the study. his is a per hour fee for the training</i>	Study Personnel	\$46	\$ 13.80	\$ 59.80
		MD/PharmD/PhD	\$165	\$ 49.50	\$ 214.50
Remote Monitoring Fee	<i>This non-refundable fee is charged per occurrence and only if applicable to the study. A stand alone letter provided for fee justification.</i>	0-3patients	\$385	\$ 115.50	\$ 500.50
		3 or more patients	\$675	\$ 202.50	\$ 877.50
Sponsor/FDA Audit Fee	Per Day Fee	\$473	\$ 141.96	\$ 615.16	
Shared Investigator Platform or Portal Fee	<i>This is a one time non-negotiable and non-refundable fee if sponsor required the use of this type of system. An example is SIP with Cognizant. If the sponsor pulls the study before start-up process is completed, they are responsible to cover the costs for the work completed on the project.</i>	\$3,000	\$ 900.00	\$3,900.00	
eConsent	<i>This is a one time non-negotiable and non-refundable fee required to electronically consent patients.</i>	\$400	\$ 120.00	\$520.00	
Serious Adverse Event (SAE) Reporting Fee	<i>This non-refundable fee is charged per occurrence and only if applicable to the study. Time and effort for clinical staff to report any SAE based on the sponsor protocol requirements.</i>	\$413	\$ 123.90	\$ 536.90	
Administrative Close-Out Fee	<i>This is a one time non-refundable fee. A stand alone letter provided for fee justification.</i>	\$2,248	\$ 674.42	\$ 2,922.47	
Archiving Fee	<i>This is a one time non-refundable fee. A stand alone letter provided for fee justification.</i>	\$935	\$ 280.44	\$ 1,215.24	
Pharmacy Start-up Fee	<i>This is a one time non-refundable fee. A stand alone letter provided for fee justification.</i>	Level I	\$ 1,733	\$ 519.90	\$ 2,252.90
		Level III	\$ 2,888	\$ 866.40	\$ 3,754.40
		Level III	\$ 5,198	\$ 1,559.40	\$ 6,757.40
Pharmacy Annual Fee	<i>This is an annual non-refundable fee. First year is charged at contract execution. A stand alone letter provided for fee justification.</i>	Level I	\$ 751	\$ 225.30	\$ 976.30
		Level III	\$ 1,127	\$ 338.10	\$ 1,465.10
		Level III	\$ 1,502	\$ 450.60	\$ 1,952.60
Pharmacy Close-out Fee	<i>This is a one time non-refundable fee. A stand alone Letter provided for justification.</i>	Level I	\$ 751	\$ 225.30	\$ 976.30
		Level III	\$ 1,155	\$ 346.50	\$ 1,501.50
		Level III	\$ 1,502	\$ 450.60	\$ 1,952.60
Hospital for Non-MHC Facility Fees	These fees may consist of the following, but are not limited to, administrative fees, pharmacy fees, and other specialties' fees for those facilities not owned by the University of Louisville or Norton Healthcare.	Amount to be determined by outside facility research offices. The University of Louisville 30% OH is required on this fee			
IRB FEES	Initial IRB Fee	<i>This is a one time non-refundable fee to the IRB which is required for document release. If the sponsor pulls the study before start-up process is completed, they are responsible to cover the IRB costs if the initial review has been completed on the project.</i>	\$ 3,000.00	\$ 900.00	\$ 3,900.00
	Annual IRB Fee	<i>This is an annual non-refundable fee to the IRB.</i>	\$ 1,000.00	\$ 300.00	\$ 1,300.00
	Central IRB Administrative Review Fee:	<i>This is a one time non-refundable fee to the IRB which is required for document release.</i>	\$ 3,000.00	\$ 900.00	\$ 3,900.00
DEVICE FEES	Medical Device Accountability Fee	<i>This is a one time non-negotiable and non-refundable fee. This fee is charged only for research studies that require devices. Time and effort associated with maintaining device accountability throughout the duration of the trial, including establishing purchase order for device tracking within our healthcare system.</i>	\$3,032	\$ 909.60	\$ 3,941.60

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Date

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Date