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Institutional Research Fee Schedule

Effective February 1, 2025

Institutional Review Board Fees (Non-Negotiable)

The Georgetown University Institutional Review Board (IRB) charges for the review of human subject research funded by private sponsors (predominantly pharmaceutical or device manufacturing companies)

(For more information, visit: https://researchservices.georgetown.edu/irb-fees/)

Institutional Review Board Review of Industry Funded Research*		
Review Level	**Review Type**	**Fee**
Full Board	New Protocol Submission	$3,000.00
Full Board	Continuing Review	$1,500.00
Full Board	Amendment	$1,000.00
Expedited Review	New Protocol Submission	$2,500.00
Expedited Review	Continuing Review	$500.00
Expedited Review	Amendment*	$500.00
Exempt Review	New Protocol Submission	$1,000.00
Expedited Review	Closure Fee	$350.00

** - IRB fees will not be applied to administrative changes such as staff changes or IRB required administrative updates.*

IRB Administrative Review of Industry Funded External IRB Submissions*		
Review Level	**Review Type**	**Fee**
Administrative	Initial Review	$2,000.00
Administrative	Annual Administrative Fee**	$1,500.00
Administrative	Close Out	$350.00
Administrative	For Cause Audit	$1,000.00

GU IRBs are required to conduct substantive and meaningful continuing review of research at intervals appropriate to the degree of risk, but not less than once per year.

Start-Up Fees[1] (Non-Negotiable)

Unless otherwise noted, the amounts listed are direct and will incur an additional 35% overhead.

Administrative Start-Up	Direct:	$10,000.00
	Indirect:	$3,500.00
	Total:	**$13,500.00**
The Administrative Start-Up Fee is inclusive of the following: completion of feasibility questionnaires, site evaluation/ pre-site selection visits, Departmental and administrative reviews, completion of internal committee applications, protocol specific trainings, protocol implementations, EDC, IVRS (etc), and the creation of the study in Oncore CTMS as well as other Hospital-wide systems		
Financial Analysis*	Direct:	$6,100.00
	Indirect:	N/A
	Total:	**$6,100.00**
The Financial Analysis includes the Creation of the study account, a thorough billing compliance review and Medicare Coverage Analysis, a Hospital compliance review, and an Advarra CTMS Calendar Build fee.		
Initial Scientific Review Committee (Oncology Only)	Direct:	$1,500.00
	Indirect:	$525.00
	Total:	**$2,025.00**
The Scientific Review Committee conducts a multi-modality Scientific and Feasibility Project Review of new studies with all departments and staff, acts as the DSMB/C for IIT trials, and serves as initial study training for investigators and support staff.		
Regulatory Prep of Initial IRB Submission	Direct:	$2,500.00
	Indirect:	$875.00
	Total:	**$3,375.00**
For the time and effort of the regulatory team for the following responsibilities: creation and provision of initial regulatory documents, including informed consent form, investigator CV, licensure, FDFs, and other study-related material, and the creation and submission of the initial IRB application.		
Radiology Start-Up	Direct:	$1,500.00
	Indirect:	$525.00
	Total:	**$2,025.00**
For the time and effort of the radiology department for the following responsibilities: Review of the imaging manual, completion of study-specific training on image capture and central radiology processing vendor (if applicable), site initiation visit between radiology personnel and sponsor/CRO, and completion + submission of phantom and qualification scans.		

Pharmacy Start-Up*: Industry sponsored studies	Direct:	$3,500.00
	Indirect:	N/A
	Total:	**$3,500.00**
Pharmacy Start-Up*: Government sponsored studies (cooperatives ECOG etc)	Direct:	$1,500.00
	Indirect:	N/A
	Total:	**$1,500.00**
Pharmacy Start-Up*: Investigator Initiated Studies	Direct:	$1,000.00
	Indirect:	N/A
	Total:	**$1,000.00**
For the time and effort of the pharmacy department for the following responsibilities: Attendance at meetings to review protocol, Protocol-specific training for storage, accountability, randomization, blinding, IVRS, Electronic inventory and sponsor accountability set-up.		
CRU Start-Up / Initiation (Non-Oncology only, When Applicable)	Direct:	$2,500.00
	Indirect:	$875.00
	Total:	**$3,375.00**
If the CRU is to be utilized, the start-up fee includes the following: CRU budget development, review of protocol feasibility for the CRU, Coordination of safety, and resource review for SEPCOM, Initiation meeting with PI and study team, Data entry training and other start-up procedures.		
CTMF Start-Up	Direct:	$3,400.00
	Indirect:	$1,190.00
	Total:	**$4,590.00**
If the CTMF is to be utilized, the start-up fee includes the following: Review and approval of all clinical trial-related documents, Site initiation visits and preparation, site SOP development, Protocol-specific site staff training, and other start-up activities.		

1 - *All applicable Start-Up fees are non-negotiable for interventional studies. All start-up fees, regardless of study type, must be paid at contract execution, if not earlier. If the contract is not executed, all applicable start-up fees must be paid.*

Annual Administrative and Pass-Through Fees

The amounts listed are direct and will incur an additional 35% overhead unless otherwise noted.

Regulatory and Administrative Maintenance	Direct:	$2,500.00
	Indirect:	$875.00
	Total:	**$3,375.00**
For the time and effort of the regulatory team for the following responsibilities: Maintenance of regulatory documents including updating CVs and licensure, correspondence, and amendments, Preparation of documents and reports for annual IRB Continuing Review, Amendment training for all research staff, Updating all applicable study logs		
Annual Scientific Committee Review (Oncology Only)	Direct:	$1,300.00
	Indirect:	$455.00
	Total:	**$1,755.00**
For the time and effort of the scientific review committee to conduct annual study reviews including enrollment, SAEs, and IND Safety Reports, and review and approve study for continuation based on scientific merit and feasibility		
Continuing Review Processing	Direct:	$1,000.00
	Indirect:	$350.00
	Total:	**$1,350.00**
For the time and effort of the regulatory team to prep the continuing review application for internal committees and local IRB		
Amendment Processing	Direct:	$800.00
	Indirect:	$280.00
	Total:	**$1,080.00**
For the time and effort of the regulatory team to prep the amendment application for internal committees and local IRB		
Pharmacy Maintenance*	Direct:	$2,400.00
	Indirect:	N/A
	Total:	**$2,400.00**
Pharmacy maintenance is calculated at a $200 per month rate which is $2400 annually. For the time and effort of the pharmacy staff for the following responsibilities: Receipt of IP and acknowledgment temperature monitoring device (if applicable), Drug accountability and maintenance of regulatory documents, Storage of IP/storage of returned IP, Procuring of commercial drugs reimbursed by the sponsor		

RECIST Criteria (per timepoint) (Oncology Only) (per timepoint)	Direct:	$75.00
	Indirect:	$26.25
	Total:	**$101.25**
For the evaluation of measurable disease, identifying target and non-target lesions, and evaluation of overall response		
Central Radiology Processing (per timepoint)	Direct:	$75.00
	Indirect:	$26.25
	Total:	**$101.25**
Time and effort of radiology staff to process image transfer to the central radiology processing vendor		
SAE Processing (per event)	Direct:	$100.00
	Indirect:	$35.00
	Total:	**$135.00**
Time and effort of study team to Collect of data for SAE source documentation, complete the SAE report and follow-up report including EDC and other required forms, file SAE reports to internal committees and local/central IRB		
IND Safety Report Processing (per report)	Direct:	$50.00
	Indirect:	$17.50
	Total:	**$67.50**
Time and effort of study team to process IND Safety reports for internal committee and local/central IRB review, if applicable		
Additional or Optional Study Informed Consent (per subject)	Direct:	$150.00
	Indirect:	$52.50
	Total:	**$202.50**
Investigator and coordinator time/effort allocated to the informed consent process if the study requires a second consent, or assent, or optional testing samples as requested		
Re-consenting of Study Subjects (per subject)	Direct:	$150.00
	Indirect:	$52.50
	Total:	**$202.50**
For the time and effort of study team to re-consent subjects as a result of sponsor-initiated protocol amendment		

Processing of Biopsy Tumor Samples	Fresh (Direct):	$300.00
	Fresh (Indirect):	$105.00
	Fresh (Total):	**$405.00**
	Archive (Direct):	$450.00
	Archive (Indirect):	$157.50
	Archive (Total):	**$607.50**
For time and effort of study team to re-consent subjects as a result of sponsor-initiated protocol amendment		
Processing of Central Lab Sample (per sample)	Direct:	$75.00
	Indirect:	$26.25
	Total:	**$101.25**
For the time and effort of the study team to re-consent subjects as a result of sponsor-initiated protocol amendment, and generally included in the per-patient budget.		
Monitoring Visits (per day)	Onsite (Direct):	$400.00
	Onsite (Indirect):	$140.00
	Onsite (Total):	**$540.00**
	Remote (Direct):	$200.00
	Remote (Indirect):	$70.00
	Remote (Total):	**$270.00**
This fee is incurred during sponsor monitoring visits and includes the time/effort related to the coordinator's availability to allow direct access to the EMR system, data manager availability for data/query review, and regulatory staff availability for regulatory document review		
Not-For-Cause Audit	Direct:	$1,000.00
	Indirect:	$350.00
	Total:	**$1,350.00**
For time and effort of study team to prep, host, and review a not-for-cause audit		
Advertisement (per study)	Direct:	$5,000.00
	Indirect:	$1,750.00
	Total:	**$6,750.00**
The sponsor and IRB must approve the text of any communication soliciting patients for study enrollment for newspaper/radio advertisements, direct mail pieces, internet communications and/or newsletters.		
Informed Consent Translation Cost		**Direct Invoice**
When utilizing a 3rd party for ICF translations, we are subject to their fee schedules and therefore pass those costs onto the sponsor when necessary.		

Additional Pharmacy Fees

The amounts listed are direct and will incur an additional 35% overhead unless otherwise noted.

Pharmacy Dispensing	Oral (PO), Topical, Inh, Inj Simple (Direct):	$50.00
	Oral (PO), Topical, Inh, Inj Simple (Indirect):	$17.50
	Oral (PO), Topical, Inh, Inj Simple (Total):	**$67.50**
	Oral (PO), Topical, Inh, Inj Moderate (Direct):	$75.00
	Oral (PO), Topical, Inh, Inj Moderate (Indirect):	$26.25
	Oral (PO), Topical, Inh, Inj Moderate (Total):	**$101.25**
	Oral (PO), Topical, Inh, Inj Complex (Direct):	$100.00
	Oral (PO), Topical, Inh, Inj Complex (Indirect):	$35.00
	Oral (PO), Topical, Inh, Inj Complex (Total):	**$135.00**
	IV, Simple (Direct):	$80.00
	IV, Simple (Indirect):	$28.00
	IV, Simple (Total):	**$108.00**
	IV, Moderate (Direct):	$125.00
	IV, Moderate (Indirect):	$43.75
	IV, Moderate (Total):	**$168.75**
	IV, Complex (Direct):	$200.00
	IV, Complex (Indirect):	$70.00
	IV, Complex (Total):	**$270.00**
This fee is assessed depending upon the complexity of the preparation process of the IP, per dispensation and generally included in the per patient budget.		

Inventory Management (per month)	Storage at Room Temperature, Direct:	$125.00
	Storage at Room Temperature, (Indirect):	N/A
	Storage at Room Temperature, (Total):	**$125.00**
	Storage at Non-Room Temperature, Direct:	$150.00
	Storage at Non-Room Temperature, (Indirect):	N/A
	Storage at Non-Room Temperature, (Total):	**$150.00**
Pharmacy: After-Hour Fees (per event)	Direct:	$500.00
	Indirect:	N/A
	Total:	**$500.00**
Pharmacy: Keeping Patient Returns (per year)	Direct:	$500.00
	Indirect:	N/A
	Total:	**$500.00**
Pharmacy: Saving Opened or Empty Vials (per year)	Direct:	$500.00
	Indirect:	N/A
	Total:	**$500.00**
Pharmacy: Send Study Monthly Temp Log (per event)	Direct:	$125.00
	Indirect:	N/A
	Total:	**$125.00**
Pharmacy: Pharmacy Randomization (each subject)	Direct:	$50.00
	Indirect:	N/A
	Total:	**$50.00**
Pharmacy: Shipping Fee (Supplier to Center, Center to Center)	Direct:	$50.00
	Indirect:	N/A
	Total:	**$50.00**

Pharmacy: Re-labeling of New Expiration Date - Simple (up to 2 bottles per dispense)	Direct:	$50.00
	Indirect:	N/A
	Total:	**$50.00**
Pharmacy: Re-labeling of New Expiration Date - Complex (> 2 bottles per dispense)	Direct:	$100.00
	Indirect:	N/A
	Total:	**$100.00**
Pharmacy: Commercial Drug Markup for Sponsor Reimbursed Commercial Supply (WAC cost plus markup)	Direct:	$200.00
	Indirect:	N/A
	Total:	**$200.00**

Pharmacy Fees cover, but are not limited to, the cost associated with the oncology research pharmacist's time and expertise and the facility requirements for the investigational products. Simple or complex assignments are made based on the intricacy of the project and/or the number of study investigational products.

- Pharmacy start-up fees include costs associated with the research pharmacist's review, planning, and set-up of the project

Pharmacy Maintenance fees (paid monthly or quarterly) include receipt, inventory, and documentation of investigational products and a fee for physical space used to store the study drugs. The fee will continue to accrue on at least a monthly basis until the sponsors retrieve the investigational product and any/all associated study materials from the MedStar Research Pharmacy.

- Pharmacy close-out fee includes costs associated with the research pharmacist's time to effect close-out of study investigational products, archiving, and storing the research pharmacy record.

*- MedStar Research Pharmacy will review and update this document **every 2 years** to reflect the current marketing situation*

Closeout Fees

The amounts listed are direct and will incur an additional 35% overhead unless otherwise noted.

Study Close-Out	Direct:	$2,500.00
	Indirect:	$875.00
	Total:	**$3,375.00**
For time and effort of study team to resolve of all regulatory and study documents including correspondence, applicable logs, and all essential regulatory documents, Collect all study-related materials and equipment for storage and/or return to sponsor, prep study files for long-term storage reconciliation		
Pharmacy* Closeout	Direct:	$500.00
	Indirect:	N/A
	Total:	**$500.00**
For time and effort of the pharmacy team for destruction/return of IP, close-out IP inventory, and participate in the study close-out visit.		
Archiving and Document Storage	Direct:	$2,500.00
	Indirect:	$875.00
	Total:	**$3,375.00**
For the time and effort of the study team to transfer study files to a storage facility, and for the monthly storage fees for the time frame required by the sponsor		
CRU Close-Out (Non-Oncology only, When Applicable)	Direct:	$1,500.00
	Indirect:	$525.00
	Total:	**$2,025.00**
Includes all study closure activities and necessary steps to ensure all aspects are addressed prior to closing the study		

* - Direct Cost Only; no applicable Overhead

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04/17/2025

Date