



CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

Clinical Research Institutional Fee Schedule

Table 1. Applicable charges by type of funding source

Source of Funding	Current overhead	Cost base	IRB	IDS			Clinical Research Center				Administrative
				Startup	Per Patient	Annual Maintenance *	Startup	Regulatory ¹	Nursing	Room	
Federal, on campus ²	67.5% ³	MTDC	NC	NC	Include	NC	NC	Include	Include	NC	NC
Federal, off campus ⁴	26%	MTDC	NC	NC	Include	NC	NC	Include	Include	Include	NC
Foundation	Set by foundation	TDC if allowed	Include if allowed	Include if allowed	Include	Include if allowed	Include	Include	Include	Include	Include if allowed
Fellowship, student, or New Investigator ⁵ (Non-Industry)	Set by funding source	TDC if allowed	Waive ⁶	Waive	Waive	Waive	Waive	Waive	Include	Waive	Waive
Department, investigator initiated	None	-	Waive	Waive	Include	Waive	Include	Include	Include	Waive	Include
CCTS funded ⁷	None	-	NC	Waive	Waive	Waive	NC	Include	Include	NC	NC
Industry	30%	TDC	Include	Include	Include	Include	Include	Include	Include	Include	Include

For charges see Table 3

Abbreviations: IDS, Investigational Drug Service (Pharmacy); IRB, Institutional Review Board; ITCTMS, Information Technology-Clinical Trial Management System, MTDC, Modified Total Direct Cost; NC, not charged (included as part of facilities and administrative (F&A) rate agreement); TDC, Total Direct Cost

1. Regulatory work for all non-industry projects (federal, foundation, department, CCTS) is capped at 2 hours until the notice of grant award is received, as pre award work cannot be charged to grants. For industry sponsored projects regulatory work may not exceed 8 hours before the clinical trial agreement is executed. For all projects, a valid charge string must be provided prior to the work beginning in the event that regulatory work exceeds the time allotted.
2. Includes all federal funding sources (eg NIH, DoD), all types of awards (e.g. K, R, P, U) and federal flow through (direct federal support of an industry sponsored trial). Allowable federal charges are those in support of post award activities; pre- award activities cannot be charged to a federal grant
3. Effective 7/1/2014

4. Off campus defined as buildings/facilities not included in the UMass F&A rate agreement; see Table 2. Off campus rates only include administrative charges, capped at 26%. Therefore, facilities fees may be charged to grants. Allowable federal charges are those in support of post award activities; pre- award activities cannot be charged to a federal grant
5. New Investigator is defined as Assistant Professor or below, within first 2 years of hiring.
6. Regulatory assistance for IRB submissions is capped at 4 hours if fees are waived.
7. Including CCTS K awards, Life Science Moment Fund, UMass Science and Technology Initiatives Fund, Pilot Project program.

Table 2. Treatment of Buildings for Indirect Cost Rates

Treatment of Buildings for Indirect Cost Rates	
<u>Buildings included in On-Campus Rates:</u>	<u>Buildings not included in schools IDC rates</u>
Ambulatory Care Center (ACC)*	Mass Biolabs Facilities
Albert Sherman Center (ASC)	Centennial Drive
Anderson House	Century Drive
Benedict Bldg - 3rd floor	Charlestown
Biotech I - 1st floor	China Trade
Biotech II	Jamaica Plains facilities
Brudnick NeuroPsych. Research Bldg	Lakeside Expansion
Chang Bldg - Shrews	Lemuel Shattuck
Farmhouse - basement	Morgan Building
fMRI (Ctr for Comp. NeuroImaging)	Prisons (Correctional Health facilities)
Foundation Barn-Shrews	QARC (Providence)
Fuller Bldg-Shrews	Schrafft
Higgins Bldg-Shrews	UMass Memorial Facilities
Hoagland Pincus-Shrews	West Exchange Street
Lazare Research Bldg (LRB)	
Machine Shop-Shrews	
Medical School	
Power Plant	
Rose Gordon-Shrews	
Shaw Building	
South Street-Bldg 1 & 2	
Stoddard-Shrews	

* Excludes space rented by UMass Memorial Medical Center. Studies conducted in the Clinical Research Center (Clinical Trials Unit) are eligible for on campus rates.

Table 3 Direct Charges by activity

Service Line	Type of Charge	Federal	Department or Investigator	Other Non Profit (e.g. Foundation)	Industry	
IRB	Start up - UMass	None	None	\$500	\$3000	
	Annual - UMass	None	None	\$200	\$1000	
	Amendment - UMass (major, full committee review)	None	None	\$100	\$500	
	Start up - Central	None	None	\$150	\$1000	
	Annual - Central	None	None	\$60	\$300	
	Amendment (major) - Central	None	None	\$20	\$100	
	IDS (Pharmacy)	Start up	None	None	\$500 if allowed	\$1250
Per patient dispense		Calculated by IDS	Calculated by IDS	Calculated by IDS	Calculated by IDS	
Annual Maintenance*		None	None	\$600	\$900	
Clinical Research Center^{1,2}	IRB submission- initial	\$50/hour or \$600 ²	\$50/hour or \$600 ²	\$50/hour or \$600 ²	Included in Startup	
	Study Start Up ^{1,2}	None	Variable	Variable	Variable, starting at \$3,000	
	Ongoing regulatory (amendments, annual renewals)	\$50/hour	\$50/hour	\$50/hour	\$75/hour	
	Nursing charge per hour	\$75/hour	\$75/hour	\$75/hour	\$100/hour	
	Nursing charge per hour (outside of CRC, weekends)	\$125/hour	\$125/hour	\$125/hour	\$150/hour	
	Full day service (Investigator meetings)	\$500	\$500	\$500	Included in startup	
	Room charge per hour	None	None	\$40/hour	\$60/hour	
	Phlebotomy Services	None	Variable	Variable	Variable	
	IND/IDE Application Services	None	\$75/hour	\$75/hour	\$100/hour	
	Administrative/CT	Startup	None	\$500	\$500 if allowed	\$1300
		Annual Maintenance*	None	\$150	\$150 if allowed	\$600
Major Amendment		None	Variable	Variable	\$650	
Medicare Coverage Analysis		None	None	None	\$1500	
Research Operations	Monitoring by HRPP QA/QI staff	\$50/hour	\$50/hour	\$50/hour	\$75/hour	
UMMC purchased services³	Laboratory, radiology	Medicare Rates	Variable	Variable	Facility: 130% of Medicare Rates Professional: 150% of Medicare Rates ⁴	

1. Start up costs based upon estimated staff time.
2. Consultation with the Manager of the CRC should be obtained for estimates of costs in developing budgets
3. Costs are based on fixed rate agreement, dependent upon source of funds, and are not negotiable.
4. Research rates are set by UMMC. These provide the lowest costs and are used for trials provided by federal, not for profit and internal funding. Industry pricing is set as a base for budget development and contract negotiations but may be negotiated. However, specific line items and total charges for purchased services must be equal to the research rate.
5. For items without Medicare charges, Office of Clinical Research will consult with applicable service provider to obtain rates. For multiyear budgets a 5% inflation factor should be applied to all budgets irrespective of sponsor
6. * Annual Maintenance fees are based on monthly rates and will be prorated upon study closure.

