

GIDELINES FOR Close-OUT costs

TIME BRACKETS, in hou

Closeout	ITEM	TIME BRACKETS, in hou	
		CRC	PI
	Closeout Report, Complete Quireies	10-15	2-3
	Box up Study Records	1.5-3	
	Transport Study Records for storage	1-2	
	Closeout Visit, Prepare for & Attend	3-4	1-3
	Regulatory close with IRB	0.5-8	
	Close out study account w/Extramural (incl.payroll transfer	0-32	
	Close out invoicing	3-4	
	Producing Addtl information after study close out	8-10	
	TOTAL	26-78	3-6

GUIDELINES FOR other Invoicable Costs

Suggested values

Adverse Events	ITEM	Suggested values
	Adverse Event, Evaluate, Report, Manage	\$75/ per AE
	Serious Adverse Event,Evaluate, Report, Manage	\$150/SAE

Site Monitoring	ITEM	Suggested values
	Answer Sponsor Inquires prior to Site Monitor Visit	\$520/day of monitoring visit
	Site Monitor Visit, Manage, Attend	
	Telephone Conference, Attend	

Annual Renewal	ITEM	Suggested values
	Prepare Annual Renewal	\$1500/year

IRB Documents	ITEM	Suggested values
	Modifications to Regulatory Documents	\$2000/year
	Regulatory Binder, Maintain	
	IRB, Communicate Modifications, incl 1572	
	Contracts, Communicate Modifications	

Admin/Correspondence	ITEM	Suggested values
	Write, Receive & Process Correspondence	\$1000-\$2000/year
	Clarify Protocol	
	Progress Report Quarterly	

Screen Failure	ITEM	Suggested values
		Charge all procedures and CRC time up to the failure