

GUIDELINES FOR START-UP COSTS

TIME BRACKETS, in hours

Protocol	ITEM	COORD	PI
	Complete Feasibility Questionnaire from Sponsor	2	2
	Review protocol & study flow	2-10	1-2
	Review by Scientific Review Committee (Cancer Ctr)	2	2
	Preparation and return of Sponsor/Site documents	2-5	0.5-1
	Pre-Study Site Selection visit, prepare for & attend	4-6	1
	Prepare, distribute, collect and copy financial disclosures	2-3	0.5-1
	Obtain and copy CV's	0.5	
	Preparatory Research	2-6	0.5-1
	CMS determination		
TOTAL		16-30	7-10

Budget	ITEM	COORD	PI
	Prepare the study budget	5-8	0.5-2.5
	Set up accounting & billing (DaFIS and Bulk) for study procedures	2-3	0
TOTAL		7-10	1-2

IRB Documents	ITEM	COORD	PI
	Informed Consent form, write, review and/or revise	5-8	0
	Protocol and Investigator's Brochure Review	1-4	0.3
	Prepare & Deliver IRB documents	5-20	
	Follow up discussion with IRB reviewers / document revision	2.5-5	1
	Prepare docs for chairman signature, deliver & pick up	0.5-2	0.3
	Radiation Safety, Biological safety	1-2	
	Scientific Review Committee, Obtain Approval (Cancer Ctr)	1	
TOTAL		16-40	2-3

Training	ITEM	COORD	PI
	Train Staff for Study/Certification	5-10	2-9
TOTAL		5-10	2-9

Pharmacy	ITEM	COORD	PI
	Correspondance with Pharmacy	1-2	0
TOTAL		1-2	0

Communications	ITEM	COORD	PI
	Correspondence with Sponsor reps	10-20	5-15
	Case Report Form Review /Source Docs Preparation	5-20	0-4
	Initial Investigator Meeting, Prepare and Attend	10-16	4-24
TOTAL		25-55	10-40

Other EXPENSES	ITEM	COORD	PI
	Advertisement/recruitment fee	based on sponsor's budget	
	Admin Expenses (office supplies, duplication, mailing)	\$1000-\$4000	
	Document Storage	\$400-\$500	
	Translation of Informed consent	\$900 for each language	
	Pharmacy Fees	\$550-\$750	