Clinical Trials Budget Worksheet (internal document)

Study Name: _____
Investigator: _____
Study Coordinator: _____

Sponsor: _____
Project Period Begins: _____

INSTITUTIONAL START-UP

Non-refundable, one time fees

IRB Fee: _____
Pharmacy Fee: _____
Regulatory Asst. Fee: _____

Subtotal: $_____

INVESTIGATOR START-UP *

Time / Effort for Protocol Assessment

Protocol Review (PI + Coordinator): _____
Site Selection Time w / Sponsor: _____
Investigator Meeting: _____
In-Service Staff: _____

This is separate from an advance

Subtotal: $_____

PER SUBJECT STUDY CHARGES

STUDY ACTIVITIES	PERSONNEL (PI/RN)	EST. HRS	FREQUENCY	TOTAL HRS. / PATIENT	FEE	SUBTOTAL
Physical Exam/Medical History						
Consent						
Screening						
Nursing assessment / Vital Signs						
Phlebotomy						
Specimen prep & Shipping						
Review of meds/protocol						
CRF Completion						
Queries/Monitor Visits						
IRB Correspondence						
SAE Forms						
Other study specific:						
Ex: CXR						
ECG						
Bone Age						
Per Patient Pharmacy Fees	**Calculated by Investigational Pharmacist**					
					SUBTOTAL	
					Institutional Overhead (26%)	
					TOTAL	

N.B. – Advertising Costs can be negotiated into the contract (usually given as a total "up to…" identified $$ amount) – paid by invoice
Will record storage need to be off-site? Negotiate one-time charge if appropriate