

## STUDY BUDGET DEVELOPMENT

***Presented by***

Phyllis Klein, RN, CCRC, BSN  
Director, Regulatory Compliance & Support  
Center for Clinical Studies  
Washington University in St. Louis  
(314) 747-4289

---

---

---

---

---

---

---

---

## OBJECTIVES

▶ **To understand:**

- ▶ How to get started when creating a budget
- ▶ What items to include in your budget
- ▶ Why your study should not bill two sources for the same procedure
- ▶ Why patients should not get billed for something the study should provide for free
- ▶ Making sure all the paperwork says the same thing

---

---

---

---

---

---

---

---

## PURPOSE:

- You need an independent review of local costs
- An opportunity to compare costs, and see if the sponsor's offered budget is adequate
- To assess whether the study is right for you based on not only reimbursement factors, but outcomes.
- Is this study right for your patient population?
- Is there an open-label follow-up study for a drug study involving a new product

---

---

---

---

---

---

---

---

### STUDY START-UP FEES...

Start-up fees are supposed to cover the effort to prepare for the study before the first patient walks through the door:

- Budget preparation & negotiations
- Contract language negotiations
- Coordinator set-up of source docs, CRF training, unpack lab kits, set-up lab/radiology accounts, etc.
- IRB review preparation
- Regulatory document preparation for the sponsor

---

---

---

---

---

---

---

---

---

---

### PER PATIENT STUDY BUDGET...

The '*per patient*' budget generates funds to pay for:

- Coordinator fees
- PI fees
- Procedure costs
- Facility fees
- Labs

---

---

---

---

---

---

---

---

---

---

### COMPUTING YOUR HOURLY RATE

	<u>hours/year</u>
Full time employee (works 261 days/year)	2,080
Less hours/vacation (22 days)=	- 176
Less unverified sick time (5 days)=	- 40
Less paid holidays (8 days)=	- 64
Actual workable hours /year	1,800
Less breaks, e-mail, etc.@ 1 hr per work day=	-225
Yielding realistic work hours/year	1575
Less mandatory training, meetings, ~hrs/yr =	-52
Less inefficiencies (times when work is slow)=	-???
Approximate possible billable hours/year	1523

---

---

---

---

---

---

---

---

---

---

## YOUR HOURLY RATE

Take the annual salary of the employee  
Add ~30% for all benefits (if academia)-you need to know the approximate percentage your company uses  
Divide by 1523 realistic workable hours  
For instance:  
▪ \$60,000 annual salary  
▪ Plus 30% (benefits) or \$18,000=\$78,000  
▪ **Divide by 1523 hours=\$51.21 per hour**  
(This # does not allow for inefficiencies when work is slow)  
Now, you have your hourly rate!

---

---

---

---

---

---

---

---

## GETTING STARTED

Now that you have your hourly rate, you are ready to start!

- Print out the schedule of events
- Read the protocol – in detail...takes notes on the schedule
- Determine what services for which you need to obtain pricing (e.g. x-rays, MRIs, RHC, biopsies; scopes, etc.)
- Are any of these services considered standard of care (SOC)?
- Identify those that are needed for the research only – your budget should only include research services.

---

---

---

---

---

---

---

---

## SCHEDULE OF EVENTS

Compare the schedule of events with the protocol requirements  
*Note: The protocol does not always match the grid!*

Determine *how long* you will need to be with the patient at each visit.

- Is there time needed to set up before the patient arrives?
- What paperwork needs to be done when the patient leaves?

---

---

---

---

---

---

---

---

## HOW MUCH TIME DOES IT TAKE?

Affix a cost for each study-related procedure based on who is involved and the time it takes. Use your hourly rate.

Obtain a price quote with a research discount for those procedures done by others (facility and professional fees)

---

---

---

---

---

---

---

---

---

---

---

---

## PATIENT REIMBURSEMENTS

**Will patient reimbursements be a factor in your budget?**

- Patient stipends / Greenphire?
- Parking fees
- Mileage
  - business rate is \$.54 per mile for 2016
  - medical rate is \$.19 per mile for 2016
- Taxi's fees
- Hotel charges

---

---

---

---

---

---

---

---

---

---

---

---

Clinical Trials Billing Matrix System										
Study ID 1488, Ver 705, Apr 12										
Protocol ID: 000777										
PI: Greenphire, LLC										
Sponsor: ACTELION PHARMACEUTICALS										
Budget By Visit										
Cost	Visit	1	2	3	4	5	6	7	8	Total
	Category	1	2	3	4	5	6	7	8	
Administration	Patient Stipend 2	\$63.00	\$63.00	\$63.00	\$63.00	\$63.00	\$63.00	\$63.00	\$63.00	\$504.00
	Phone	\$10.00	\$10.00	\$10.00	\$10.00	\$10.00	\$10.00	\$10.00	\$10.00	\$80.00
	CTC Facility Fee	\$37.00	\$37.00	\$37.00	\$37.00	\$37.00	\$37.00	\$37.00	\$37.00	\$296.00
	City Fee	\$11.00	\$11.00	\$11.00	\$11.00	\$11.00	\$11.00	\$11.00	\$11.00	\$88.00
Coordinator Services	Education/Concert	\$94.50								\$94.50
	Education/Concert Online	\$94.50								\$94.50
	Management	\$25.20								\$25.20
	Medical History for Study	\$94.50								\$94.50
	Site Visit/Travel	\$25.20	\$25.20	\$25.20	\$25.20	\$25.20	\$25.20	\$25.20	\$25.20	\$201.60
	Travel/Travel	\$50.40	\$50.40	\$50.40	\$50.40	\$50.40	\$50.40	\$50.40	\$50.40	\$403.20
	Site Visit/Travel	\$50.40	\$50.40	\$50.40	\$50.40	\$50.40	\$50.40	\$50.40	\$50.40	\$403.20
	Site Visit/Travel	\$25.20	\$25.20	\$25.20	\$25.20	\$25.20	\$25.20	\$25.20	\$25.20	\$201.60
	Medical Shipping/CR	\$25.20								\$25.20
	Medical/Research/Regulation	\$25.20								\$25.20
	Qualifications	\$25.20								\$25.20
	CR Completion	\$100.80	\$100.80	\$100.80	\$100.80	\$100.80	\$100.80	\$100.80	\$100.80	\$806.40
	Monitoring/CR	\$50.40	\$50.40	\$50.40	\$50.40	\$50.40	\$50.40	\$50.40	\$50.40	\$403.20
	Regulatory/CR	\$25.20								\$25.20
REGISTRATION & ADMINISTRATION	Regulatory/CR	\$100.80								\$100.80
REGISTRATION	REG	\$25.20								\$25.20
REGISTRATION	Per Page & Document Record Fee	\$25.20	\$25.20	\$25.20	\$25.20	\$25.20	\$25.20	\$25.20	\$25.20	\$201.60
	<b>Total Budget Including Overhead (20%)</b>	<b>\$1,186.70</b>	<b>\$636.30</b>	<b>\$475.50</b>	<b>\$447.30</b>	<b>\$447.30</b>	<b>\$447.30</b>	<b>\$447.30</b>	<b>\$447.30</b>	<b>\$4,736.20</b>

---

---

---

---

---

---

---

---

---

---

---

---



Clinical Trials Billing Matrix System  
Budget Startup Costs

Study ID: 5466, Ver: 700  
Project ID: 300777  
PI: Neuroscience, Strat  
Sponsor: ATTELOW/PHARMAC/CHOW

Item	Initial Price	Annual Price	PIR Dates	Comments
<b>Initial Costs &amp; Recurrent Items</b>				
IRB Initial Review Fee	\$1,100.00			
IRB Annual Review Fee		\$1,000.00		
Regulatory of change to the IRB ICF history (signature)			9/25/16	
Regulatory & Initial IRB Preparation Fee	\$3,500.00			
Annual Regulatory & Preparation fee		\$1,000.00		
Amendment Processing fee			6000.00	
Coordinator Start-Up fee	\$2,500.00			
Research Pharmacy Initial fee	\$1,225.00			
Research Pharmacy Annual fee		\$1,000.00		
Document Archiving	\$1,000.00			
Advertisement & Recruitment	\$5,000.00			
Pre-Screening Funds	\$2,000.00			
Quora Services			\$1,160.70	
IRB at our site			\$700.00	
Review/Submission of IRB safety reports			\$25.00	
Recommending site to ICF change			\$75.00	
<b>Total Costs</b>	<b>\$8,325.00</b>	<b>\$3,000.00</b>	<b>\$3,130.70</b>	

Budgeting/Doc, Rev 17/2014      MCF/Pharmacy      User Role: Budget      Page 1 of 1

---

---

---

---

---

---

---

---

---

---

**PRE-SCREENING TIME**

**Industry sponsors do not always want to cover the cost of pre-screening of potential patients**

- Include time in your screening visit
- Ask for a Start-Up fee to cover this effort
  - Pre-screening fee
  - Recruitment/Advertising fee

**NIH format of providing an FTE covers this effort**

---

---

---

---

---

---

---

---

---

---

**EXAMPLES OF FEES**

**These are examples of fees we try to recover in the budgets we negotiate for effort in preparing for study start-up:**

- Initial IRB Prep & Regulatory     \$ 3,500
- Annual IRB Prep & Regulatory     \$ 1,000
- Amendment Prep & Processing     \$ 700 each
- Coordinator Start-Up                \$ 2,500
- Investigator Feasibility & Review    \$ 1,000

---

---

---

---

---

---

---

---

---

---

**MORE FEES...**

Med Storage (locked cabinet)      \$500-\$1000

Research Pharmacy costs  
(not needed if you store/dispense yourself)

- (Initial and annual fees + OH)      \$1500 - \$700

Advertising/Recruitment      \$5,000 or

Pre-screening funds (charts)      \$2,000

Document Archiving      \$1,000

- Remember, it's for up to 15 years

---

---

---

---

---

---

---

---

**COVERING YOUR COSTS...**

**Patient Stipend – sponsor's amt      \$ 50**

**Parking fees      \$ 15 day**

**CRF Completion/SM      \$ 75/hr**

- (Your cost plus extra for unexpected events)

**Be sure to include enough hours for the coordinator.**

- Sometimes the paperwork may take 2 hours per patient visit. Sometimes, there is an hour before the visit to consider, too!
- **Local labs or Central lab?**

---

---

---

---

---

---

---

---

**BE ABLE TO JUSTIFY YOUR COSTS**

Consenting & documenting I/E

Phlebotomy – \$60-\$75/hour RN or \$30-\$35/med tech

- ½ hour

Lab Processing - \$60-\$75/hour RN or \$30-\$35/med tech

- ½ hour or more

Vital signs

Height – Weight

Con med review

---

(Refer to the hourly amount you calculated)

---

---

---

---

---

---

---

---

MEDICATION PREP...

**Medication dispensing** - Who is doing it? Pharmacy or coordinator or both?

**Med accountability** - Is this the pharmacy's responsibility or the coordinators?

**Are there prophylactic meds that need to be dispensed?**

**Is this a device that needs prophylactic meds administered?**

---

---

---

---

---

---

---

---

SOMETHING TO THINK ABOUT

When figuring the fee to do an infusion or ECG, remember the costs of equipment maintenance (calibrations)...these *expenses* should be included in the cost of the procedure:

For example, we allow:

- IV Pump use & supplies, per infusion     \$25
- EKG machine                                     \$25
- So if the infusion takes 1 hour @ \$75 then the charge per infusion should be \$100 (\$75 nurse + \$25 pump) OR have a small fee for supplies in the administrative portion of your budget.

---

---

---

---

---

---

---

---

COVERING YOUR COSTS

Monitoring Visits (with Sponsor's rep)  
@\$60-\$75/hour – add ~½ hour per patient visit (e.g. \$35-\$40 per visit)

*Sponsors will tell you that these expenses are part of the cost of doing business, but you need to account for this somewhere!*

Usually when monitors come, they monitor more than one chart/visit– so the ½ hours you add-in will add-up to cover your time overall

---

---

---

---

---

---

---

---



### PI FEES

- PI fee –We figure \$50 per study visit /per patient unless PI specifies something different (to oversee study)
- If in doubt, ask your principal investigators what amounts they would like to include
- This fee covers their time to sign off on paperwork and meet with coordinator weekly.

---

---

---

---

---

---

---

---

### HOURLY FEES

Regulatory/Coordinator work, by the hour,  
\$60-\$75/hour (depends on the salary of the employee)

CHART REVIEW, by the chart, \$35 per patient (FYI: ratio  
of 3 screened to each enrolled)

---

---

---

---

---

---

---

---

### NEGOTIATIONS

Industry sponsor's usually have a little wiggle room on their budgets...

It used to be about 30% before they need approval from the next level up.

With the cost cuts, the Sunshine Act, and fair market value, it is now less

Don't be afraid to ask for what you need, all they can say is no!

---

---

---

---

---

---

---

---

BUDGET AT YOUR COST...

**These studies need to be budgeted at your cost:**

- Any studies funded by:
  - NIH
  - Collaborative Groups funded by NIH
  - Department of Defense
  - Center for Disease Control

---

---

---

---

---

---

---

---

FEDERALLY FUNDED STUDIES:  
WHAT IS COST?

For labor: it is the salary plus benefits for an employee—many times you name the employee

If this is the case, you will budget for an FTE (full time equivalent) of an individual's salary

---

---

---

---

---

---

---

---

DETERMINING COSTS:  
PROCEDURES & SUPPLIES

Many times, there are two different rates for procedures - industry & federal

When requesting costs for a *federally* funded study, tell your contact that the study is federally funded so that they can provide you with the correct price quote.

This applies to quotes for labs, x-rays, hospital procedures, room rates, etc.

---

---

---

---

---

---

---

---

## OVERHEAD

**The overhead rate for federally funded studies may vary depending on the study**

- You will need to find out the overhead rate from the group that typically handles your grants (our rates is 54%)

**The overhead rate for industry sponsored studies at WU is :**

- 26% dean's overhead
- +5-11% department overhead, if applicable

---

---

---

---

---

---

---

---

---

---

## PATIENT COSTS – WU OPINION

Patients are responsible for any co-pays or deductibles that are part of their insurance plan if the procedure is billed to insurance.

We CANNOT reimburse the cost of the co-pays or deductibles even if the study sponsor wants to provide this funding for us.

It could be construed as a violation of the federal anti-kickback statute for the healthcare provider to waive the patient's co-pays/ deductibles, and viewed as an inducement or coercion for the patient to participate.

If covered by the study budget, you MUST pay for the entire procedure from the study funds—you cannot allow the patient/insurance company or Medicare to cover even part of the cost.

---

---

---

---

---

---

---

---

---

---

## MIXING RESEARCH WITH ROUTINE CARE

### Benefits:

- Streamline patient care
- Lower costs 'per patient' for sponsor

### Issues:

- Risk that patient insurance will be denied if their healthcare insurance policy does not include research participation
- Potential for billing errors (double billing)
- More coordinator time to protect patient
- More administrative time to correct billing errors

---

---

---

---

---

---

---

---

---

---

### SOC VERSUS INVESTIGATIONAL

Charges covered in your study budget *cannot* be billed to another source – *double-dipping* is illegal!

If standard care dictates, and the procedure will be paid by patient insurance or Medicare, then you *cannot* have the cost in your study budget

If the informed consent says the patient will not pay for certain services, then they *cannot* be charged, and neither can their insurance company or Medicare – if promised free, it's free! Make sure the ICF is in parity with the budget!

---

---

---

---

---

---

---

---

### WU BILLING COMPLIANCE RULES

#### Insurance Denial Language

- Most-favored-nation type rule: another payor cannot be treated better or given a better deal than Medicare is given
- Medicare is always secondary payor (MSP rule)
- If Medicare has agreed to cover the cost of a device or procedure, but a health insurance provider denies coverage and the sponsor pays the bill...guess what? - the Medicare patient will also then get the procedure paid for by the sponsor

---

---

---

---

---

---

---

---

### PRE-CERTIFY PATIENTS FOR INSURANCE COVERAGE

Since not all insurance plans cover patients participation in research, if your study involves any routine coverage (insurance billing), it is helpful to know if the patient's insurance will allow their participation.

If the answer is 'no', then the study must pay for everything, or the patient must not participate. It wouldn't be fair to burden your patient with medical bills that could have been avoided.

---

---

---

---

---

---

---

---

STUDY BUDGET DEVELOPMENT

- **Questions ?**

- If you have questions, there is a mechanism in place for them to get to me.
- I will answer them via e-mail
- Thank You!

---

---

---

---

---

---

---

---