


NEGOTIATING CLINICAL TRIAL BUDGETS

Debbie Williams
R.N., C.C.R.C.,
C.R.A., A.B.N.





A.B.N.

Amateur Budget
Negotiator





OVERVIEW

- Budget Types
- Analyzing the Protocol
- Negotiating the Contract
- Discussion / Tips

Goals

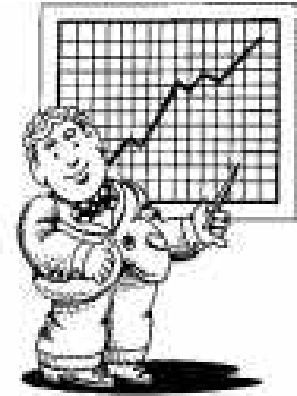
- Participate in the development of new treatments and medicines



- Recognition

- Part of Hospital Mission Statement

And.....



Profit Margins



The Bottom Line...

...Is Not Always The
Bottom Line



TYPES OF BUDGET



- ITEMIZED PER SUBJECT
- STUDY BUDGET (Set-up, Investigator Fees, Pharmacy fees etc.)
- PRESET BUDGET (Lump sum)

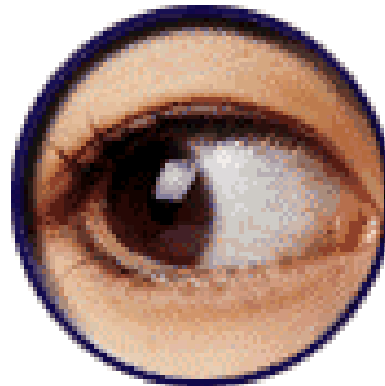
3 “EASY” STEPS

- Review (*What is involved with this study?*)
- Determine Profit (*What is the profit margin?*)
- Revise (*Negotiate*)



ANALYZING THE PROTOCOL

- **Feasibility**
- **Focus quickly on whether or not you can/want to do study**



Investigator Motto

- *Just Do It*



Available Resources

- Patient Population
- Staff to properly conduct study – Study Coordinator and Nurses
- Access to specialized tests / equipment such as CT, MRI, refrigerated centrifuge etc.
- Is Medical Coverage required?



Do you have the patient population?



If not:

Cost of Recruitment

Advertising

Stipends

Staffing

- Principal Investigator
- Sub-Investigators
- Study Coordinators
- Nurses
- Lab
- Pharmacy
- Etc.



Specialized Equipment / Tests

- MRI
- CT
- Cardio
- Pulmonary Function tests
- Day beds
- Refrigerated centrifuge ...



STUDY SCHEMATIC

Schedule of Assessments

- Good synopsis of study requirements
- Create a template to roughly estimate costs

Institutional Costs

25% Overhead



Cost and Charge

- Find out what a procedure or test actually costs
- Charge a higher rate to sponsor

Staffing Costs

- Do not quote actual hourly rate.
- Inflate salary to cover benefits, vacation pay, sick pay coverage, overtime, raise increases for study personnel (for studies of long duration)

Investigator Fees

- Need to factor this in with itemized budget formats (as well as lump sum budget)
- Follow MSP rates for physicals, medical histories – usually \$150 - \$200 / hour
- Consider time for meetings, reviewing and signing CRFs, DCRs, etc.

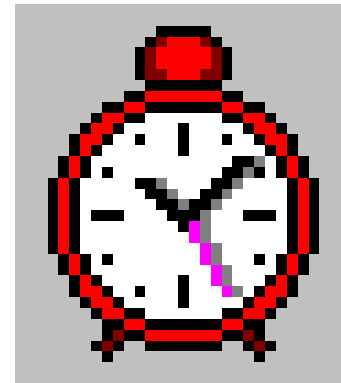
Pharmacy Fees

- Set-up fee of \$1000 – whether or not you actually enroll subjects
- Dispensing fee – approximately \$15
(could be more depending upon workload)



Coordinator Time – Pre study

- Read protocol
- Prepare budget
- Pre-Site visit
- Obtain hospital approval
- Prepare submission to IRB
- Train study staff / nursing staff
- Attend Investigator's meeting
- Organize Initiation meeting



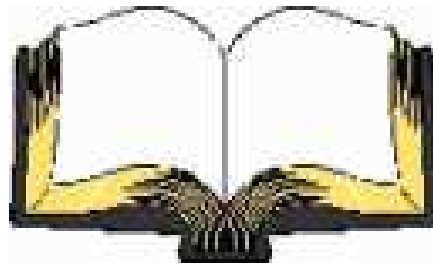
Coordinator – during study

- Screening
- Consenting
- Enrolling subjects
- Subject visits and procedures
- CRF completion
- DCRs
- MedWatch reports / SAEs
- Enrollment logs



Coordinator – during study

- Make sure to ask for at least the draft CRF before signing budget
- CRF could be very lengthy and complicated
- On-call for study enrollment



Coordinator – study close

- Preparation for site close-out visit
- Storage of documents – what is this going to cost you?
- Letter to IRB

STUDY AUDIT

Possibility of Audit (Sponsor or Regulatory) is great – especially if you are a high enrolling site.

- What is the time involved?
- Ask for a amount up and above the “lump sum” dollar figure.

Other Costs to Consider

- Screen failures – common
 - Coordinator time – consents, arranging appointments
 - Lab costs
 - Investigator time
 - Screen failure CRF completion
 - Clerical time



Solution

- Ask for screen failure reimbursement
- Some companies are okay with this, others have policy not to pay
- Doesn't hurt to ask



		PER PATIENT COSTS					
Assessment		Number of Times	Item Cost	Total Cost	Item Cost Charged	Total Cost Charged	
Informed consent		1	35	35	50	50	
History		1	50	50	75	75	
Physical Exam		2	50	100	100	200	
Vital Signs		6	0	0	0	0	
Serum Pregnancy		2	25	50	35	70	
ECG		6	35	210	50	300	
Chest Xray		2	50	100	75	150	
Hematology		6	30	180	45	270	
Clinical Chem		6	25	150	35	210	
Virology	Hep B	1	25	25	30	30	
	Hep C	1	20	20	25	25	
	HIV	1	20	20	25	25	
Drug Screen		2	30	70	35	70	
Urinalysis		2	9	18	15	30	
Randomization		1	30	1	40	40	
Drug Dispensing fee		5	15	75	20	100	
Pharmacokinetics		4	30	120	40	160	
Coordinator hours		10	30	300	40	400	
CRF Completion		6	30	180	40	240	
Subject Stipend		1	125	125	125	125	
Total per Patient				1829		2570	

Total per Patient				1829		2570	
		Profit Margin per subject = >40%					

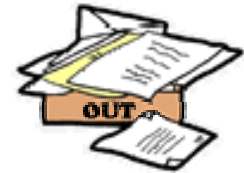
Other Costs continued...

- Redraw or repeat of blood samples/tests (budgeted for only one)
- SAEs can be costly in time – ask for reimbursement in budget.
- Copying and shipping of films
- Preparation of study specific blood samples
- Dry ice
- Patients not compliant or do not finish study
- Protocol amendments

START UP COSTS

Pharmacy Fee	1000
Submission to IRB	750
Study Set-up	1000
Attendance at Meetings (Investigator's and Site Initiation)	1000
Administrative Expenses (Phone calls, Faxes, FEDEX, includes Coordinator time)	500

TOTAL = \$4250



Alternate Solution

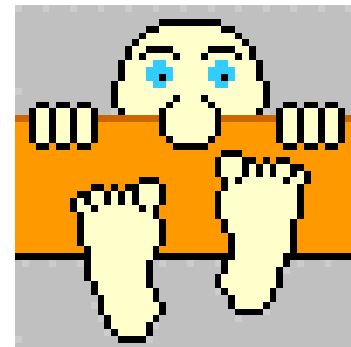
- Ask for study start-up fee apart from patient enrollment fee
- One time charge
- \$5000 ?

Get Definition of Subjects for Payment Purposes!

- Consented
- Enrolled – Randomized
- Randomized but did not receive drug
- Subject withdraws consent
- Subject lost to follow-up
- Subject completes study

BIG COST TO SITE

- Premature cancellation of study due to safety or efficacy concerns!
- Need to ask for compensation in budget to cover this.



Other Pass-Thru Costs to Negotiate

- 25% overhead
- Screen failure reimbursement
- SAEs (if expecting several)
- Copying and Shipping of Films
- Dry Ice for Shipping
- Audits – *What's your time worth?*
- Document Long-term Storage

ADDITIONAL REQUESTS

- Screen failure \$25.00
- SAEs \$100.00
- Film Copying \$25.00
- Dry Ice \$25.00
- Audit \$200.00

Other Costs continued...

- “Incentives” to staff

- Increases compliance with study protocol
- Makes staff more aware of research being conducted
- Good attitude adjuster

Can generally ask monitor to get permission from sponsor during study for these perks.

Get On The Phone



- Talk to other sites conducting study
- Try to go in together with same budget expectations – power in numbers
- Talk to Sponsor budget department – state your case for more money with specific examples
- Involve PI

U.S. Sponsor



Ask for U.S. Dollars

50% profit
immediately

IT DOESN'T HURT TO ASK

All they can do is say no!





ASK YOUR COLLEAGUES

Share Information
Draw on Experience

