



Clinical Trial Budgets

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Types of Funding

- Federal Grant: National Institutes of Health, NHLBI, NCI
- Private Granting Agency: American Heart Association
- Industry Sponsored: Pharmaceutical/Device Co.
- Investigator Initiated: No funding, Private funding

Clinical Trial Budgets

Research trials are designed to answer a scientific question, however, they **MUST** make sense,
Financially

Research sites must be careful to determine if they can afford to do a study,
Without Losing Money



Federal Budgets

Applying to the NIH



- ***Keep in Mind:*** The budget is the financial representation of the statement of work
- Costs are listed as either direct or indirect costs (means whether F&A is assessed or not)

- **Reasonable:** A prudent business person would have purchased this item and paid this price
- **Allocatable:** It can be assigned to the activity on some reasonable basis
- **Consistently Treated:** Like costs must be treated the same in like circumstances, as either direct or indirect costs

*(*eligible for reimbursement by the federal government.)*

What Does "Allowable" Mean?

- Costs that can be specifically identified with a particular project or activity:
 - Salaries and Wages
 - Fringe Benefits
 - Equipment <\$5000
 - Expendable Supplies and Materials
 - Travel
 - Subcontracts <\$25,000
 - Consultants
 - Other

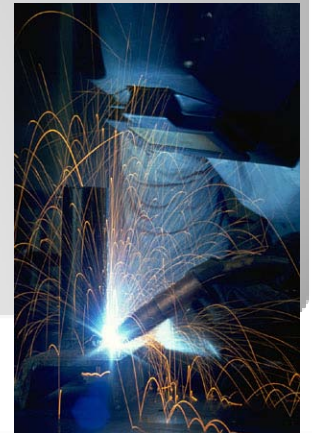


<http://www.uth.tmc.edu/finance/paf/pdf/GrantGuide.pdf>

Direct Cost Items

- List names of all who will be involved on the project during initial period, regardless whether or not salary is being requested
- Identify the role of each individual listed
- NIH salary limit is \$199,700
 - Fringe benefits amount based on annual salary (refer to Benefits Tier)

Salaries and Wages



- Costs incurred for common or joint objectives, that cannot be identified readily and specifically with a particular sponsored project, an instructional activity, or any other institutional activity
- Examples of F&A Costs:
 - Salary of department administrator
 - Building utility and maintenance costs

Facilities & Administrative Costs (formerly called Indirect Costs)

Facilities & Administrative Costs

- Industry Contracts – 30% of total direct costs (all costs)
 - No exclusions
- Federal Grants- 50% of certain direct costs, (known as modified total direct costs, MTDC)

IDC Exclusions:

- Costs of routine care for research participants (X ray, ECG)
- Tuition and fees
- Alterations and renovations
- Subcontracts
- Equipment greater than \$5000/unit
- CPHS review fee



Industry Budgets



U.S. Food and Drug Administration
Protecting and Promoting Your Health

Industry contracts

- Protocol
 - Review schedule of events
- Clinical Trial Agreement
 - Review and pay attention to budget section
 - Forward to Office of Sponsored Projects
- Sponsor's reimbursement schedule
 - Review



Feasibility Assessment

- Investigator involvement/interest
- Subject risk/ science is important
- Validate enrollment potential
- Infrastructure feasibility
- Reevaluate before signing contract

Successful sites know when to say NO!

Harper, B, Fixing feasibility, ensuring a successful fit of the protocol and your site, Aug 2010, MHRI Lecture series

Hints to Assess Feasibility

- What and how have you done research in the past?
- What is your Site Profile?
 - Expertise
 - IRB time
 - eCRF experience
 - Metrics



Questions to Consider

- What is the payment schedule/patient?
- Are all patient expenses included?
- Where is administrative time?
- Are pharmacy costs adequate?
- Do we have shipping costs?
- What is payment if a patient discontinues?

Study start up items

- Costs for items needed prior to study start
 - IRB application fee
 - IRB submission
 - informed consent development
 - pharmacy start up fee
 - administrative fees (budget development/ negotiation)
 - Clinical Research Unit processing fee
- Nonrefundable
- Should reflect indirect cost in the estimate



Other costs

Necessary study management costs, not customarily start up or charged per patient

- Travel
- Advertising
- Records Management
- Special Equipment
- Dedicated fax line
- Computer and printer
- Supplies
- Dry Ice

How will you bill these?



Per Patient Costs

- Identify what is standard of care vs research
- Obtain price for research items

For UT, see UT Price List:

<http://www.uth.tmc.edu/ctrc/budgetdevelopment.html>

For MHHS, see CRU budget page

<http://ccts.uth.tmc.edu/ccts-services/clinical-research-units>

- Record how many and when the items will be done
- Ensure all related costs are included

28 C. PER PATIENT COSTS:	Standard of Care (SOC) vs.	Screening Visit	Visit 1	Visit 2	Visit 3	Visit 4	Last Visit	Total		
29 EFFORT-BASED Time and COSTS	Research (R)									
30 Informed Consent		50.00						50.00		
31 Inclusion/Exclusion Criteria		25.00						25.00		
32 Chart Review		25.00						25.00		
33 Medical History		100.00	x				x	100.00		
34 Vitals & Blood Pressure								-		
35 Physical Examination								-		
36 Review Adverse Reactions								-		
37 Other CRF completion		50.00	x				x	50.00		
38 EXPENSE-BASED COSTS										
39 Clinic Visit										
40 CRU	Research (R)	50.00	50.00				50.00			
41 X rays & Scans										
UTP chest xray 2 views charged with CRU	Research (R)	28.86	28.86				28.86			
42 ECG										
43 Medication Dispensing/Returning	Research (R)	30.00	30.00				30.00			
44 Out-patient Tests/Procedures (itemize below)										
45 Professional Fees (itemize below)										
UTP radiology	Research (R)	11.05	11.05				11.05			
46 Urine & Blood Workup Send out	Research (R)									
47 Supplies										
48 Patient Stipend										
49 Patient Parking	Research (R)	15.00	15.00				15.00			
50 Other										
51 SUB-TOTAL PER PATIENT COSTS		-	384.91	134.91	-	-	-	134.91	654.73	654.73
52 NUMBER OF PATIENTS										10.00
53 SUB-TOTAL PATIENT COSTS									-	6,547.30
F&A costs CONTRACTED AMOUNT			500.38	175.38				175.38		

Personnel Costs

- Personnel with Direct Responsibilities on the Trial
 - Principal Investigator
 - Coordinator
 - Co-Investigator



- Use the Expense Based Category to help determine the
% effort needed in the budget

Other Invoiceable Items

- Screen Failures
- Monitoring Visit
- Unscheduled Visits
- FDA Audit
- Telephone calls
- Amendments/Continuing Review submission



How/when will these charges be identified and billed to the sponsor?

Hidden Costs

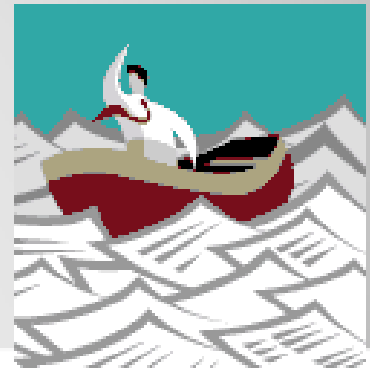
- Typically, > \$2,000 in hidden costs per study are not being identified in budget at site and not being reimbursed by sponsors
- Many costs are underestimated



Woodfin, Karen E. The CRC's Guide to Coordinating Clinical Research. Boston, Mass: CenterWatch, 2004.

Under-estimated Effort Costs

- IRB application submission (~ 8-12 hrs)
- Informed consent development (~ 4-5 hrs)
- Compiling regulatory documents
- PI effort
 - Protocol oversight
 - CRF review
 - Adverse event review



Hidden Study Management Costs

- Time is money
 - SAE reporting to the sponsor and the IRB
 - IND Adverse event reporting
 - Lab processing and shipping (~1 hr)
 - Queries
 - Sponsor visits
 - Phone calls
- Indirect costs on IRB submission and continuing review fees



Points to Remember

- Diagnostic tests have 2 components:
 - Technical component (tests - MRI)
 - Professional component (interpretation - report)
- Study staff's time/effort – hourly or effort based
- Study services are SOC or Research only
- CPHS policy:
 - *services which are research only or done as a result of research injury to patients may not be billed to patient, provider or Medicare.*

Look at the costs, then....

- Decide how important is it to do this study
 - Previous history with sponsor
 - Establish history with sponsor
 - Relevance to science
 - Experience with investigational product
 - Subject population
 - Makes sense financially

Fedor, Carol A. Responsible Research, A Guide for Coordinators. London, UK: Remedica, 2006.

Sponsor Negotiation

- Federal Grants
 - No negotiating
 - Must recover costs of billable items
 - Certain amount of money is allocated for research services
 - Must disclose any additional funding for project
- Private
 - May have negotiating room
 - May negotiate overhead (IDC) negotiation according to agency policy

Negotiating Industry Contracts

- Know the cost will be higher than they suggest
- Work from sponsor's budget template
- Be able to justify costs of study
- Base costs on service per patient
- Do not include salary information
- "Pass through" costs (*costs excluded from IDC*)

Sponsor Negotiation

- Talking points with Sponsor:
 - Geographical location of this site
 - History with investigator
 - Subject population – easy or difficult to recruit
 - Previous research metrics
- Ask for start up costs, up front, nonrefundable
- Amendments that expand scope of trial
 - Re-negotiate extra billable items

References

- Fedor, Carol A. Responsible Research, A Guide for Coordinators. London, UK: Remedica, 2006.
- Woodfin, Karen E. The CRC's Guide to Coordinating Clinical Research. Boston, Mass: CenterWatch, 2004.
- Office of Acquisition Management and Policy at the National Institutes of Health. DFAS-FAQ, Indirect costs. Available from ocm.od.nih.gov/dfas/faqIndirectCosts.asp#difference. Accessed June 13, 2006.
- Catherine Carter, BSN, RN, CCRC

Thank you very much!