Penn Medicine

Sponsorship Economics and Practicalities of Clinical Trials : Budgeting and Building a Budget

RSNA CTWS

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Disclosures: None

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Learning Objectives

- Understand the building blocks of a Budget
- Understand the general rules and expectations for each part of the budget

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Building a Budget

What Are the Costs?

- Personnel (generally 60-80+%)
- Equipment & supplies
- Clinical care costs
- Subject recruitment, animal costs
- Regulatory & administrative fees
  - many not allowable on federal grants
- Archival & document retention fees

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Direct vs. Overhead Costs

- Direct costs
  - costs of activities directly related to research
  - for personnel, does include fringe benefits
- Overhead (indirect, or F&A) costs
  - costs of activities related to infrastructure
    - administrative assistants
    - business administration
    - space costs
    - IRB costs
  - often ≥50% of direct costs
    - these are institution specific, generally cost-based, result from ongoing negotiation with NIH

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Personnel Costs

- Personnel involved in imaging studies
  - principal investigator
  - co-investigator
  - technicians/technologists
  - data management
  - biostatistician
  - readers
- Personnel costs are generally largest single component – be realistic
  - too low on PI – warning, especially if junior
  - too low on collaborators – reviewers doubt you will get any input/involvement from them
  - May vary over the course of a trial
  - Note: Key Personnel have increased reporting requirements

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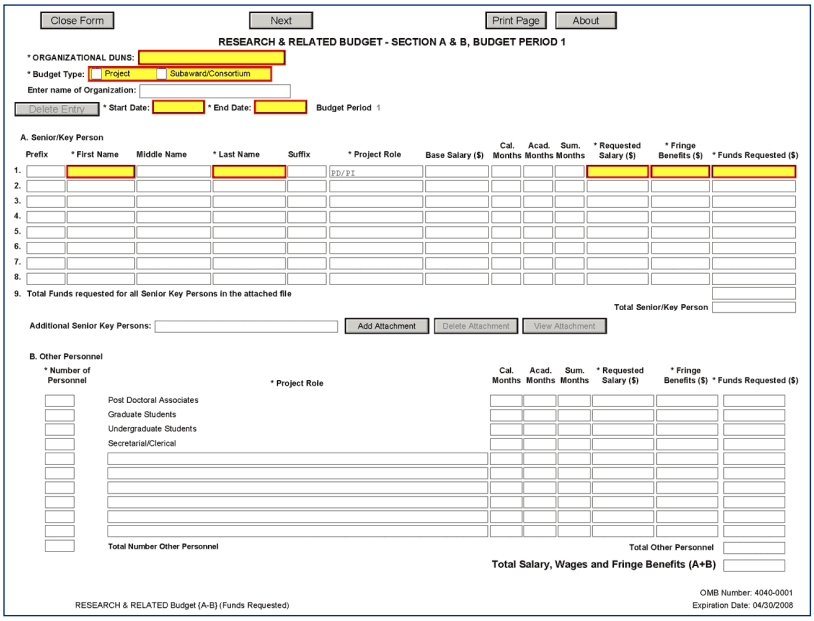

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RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

* ORGANIZATIONAL DUNS:

* Budget Type: Project Subaward/Consortium

Enter name of Organization:

Delete Entry | * Start Date: | * End Date: | Budget Period 1

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.						PD/PI							
2.													
3.													
4.													
5.													
6.													
7.													
8.													

9. Total Funds requested for all Senior Key Persons in the attached file

Total Senior/Key Person

Additional Senior Key Persons: | Add Attachment | Delete Attachment | View Attachment

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						

Total Number Other Personnel — Total Other Personnel

Total Salary, Wages and Fringe Benefits (A+B)

RESEARCH & RELATED Budget (A-B) (Funds Requested)

OMB Number: 4040-0001
Expiration Date: 04/30/2008

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Principal Investigator

- Overall responsibility for study
- May delegate some activities, but should have demonstrated competence in most
- Responsibilities include:
  - scientific leadership
  - operations
  - finances
  - regulatory
- Effort for entire trial, including start-up, recruitment, data analysis, manuscript writing, publication

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Co-Investigators: Imaging Trials

- Clinical colleague(s)
  - radiologist(s) – image interpretation
  - non-radiologist clinician – patient recruitment
  - surgeon/pathologist – specimen procurement
- Basis scientist(s)
  - develop, support imaging technology
  - radiochemistry, contrast agent development
  - imaging/device quality control
- Effort based on role, typically greatest during active recruitment/data collection phases

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Project Support/Assistance

- Study Coordinator
  - recruitment, scheduling, data procurement
  - record maintenance
  - may manage regulatory approvals
  - +/- role in financial management
- Technician/technologist
  - conduct experiments
  - image/data analysis
- Effort generally for entire study period, including start-up, recruitment, analysis

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Estimating Effort: Project Support

- Estimate actual time for research activities associated with study … then inflate to cover administrative effort, training & invariable underestimation of effort (50-100%)
  - example: if you estimate 4 hours for patient recruitment, imaging & data entry, assume the cost to you is 6-8 hours & budget accordingly
- Note: estimation of costs for co-investigators is similar, except that you can often run into budget limits with too many co-investigators

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Data Management/Biostatistics

- Develop data entry forms
- Develop study databases
- Monitor/QC databases/correct of data input?
- Effort generally largest during start-up phase (design/test systems), then again in analytic phase (data clean-up and pre for stats) – but also for interim analysis (DSMB) – completeness and quality of data, target population, prevalence of disease, endpoints

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Biostatistics

- Develop analytic plan – pre-submission
- Provide updated SAP and SMP
- May oversee data management
- Monitor progress towards endpoints
- Interim analysis and reports
- Interface with monitoring body
- Data analysis and manuscript preparation
- Effort greatest for design & analytic phases

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Fineberg's Hierarchy

- Technical Performance
- Diagnostic Accuracy (sens/spec)
- Impact on Diagnostic Thinking
- Impact on Therapeutic Planning
- Patient Health Outcomes
- Costs & Benefits to Society

Level does often correlate with complexity of the study

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How To Do The Right Trial?

Match the complexity of the trial with your personal capabilities and your environment

- Do you have enough clout to ensure proper conduction of the trial?
- Do you fulfill expectations of the PI position?
- Do you have a strong mentor and departmental support for your idea?
- Do you have strong collaborations to areas where you are not an expert in?

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Single Center Accuracy Study Vs. Multicenter Outcome Trial

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Single Center Accuracy Study

- 100 patients, one site, one time point, one modality to pay for
- Typical Time Frame: One to Two Years / one to two patients per week
- Unlikely to require DSMB
- Limited group of collaborators
- May be CRC, stat support, some data support
- three year grant – 750k to 1 Mill Dollar (modular vs. non-modular budget)

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Multi Center Outcome Study

- 1000 patients, ten sites, multiple time points, one modality to pay for
- Typical Time Frame: Five Years (initially)
- Requires DSMB
- Large group of collaborators, professional data and stat center support
- Run-in phase, 2 year enrollment, FU closed after 4.5 years – one patient per week per site
- often not possible within regular NIH budget (<500k direct per year)

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Study Plan - Patient Visits, Testing, and FU

	Screen	Day 0	1 mo	6 mo	12 mo	18 mo	24 mo	Q 6 mo	Q 12 m
Main Study (8-10 sites) (N=1000)									
Physical exam	x	x	x						
Screening blood	x								
Blood Biomarkers	x		x	x	x		x		x
Clinical visits and assessments	x		x	x	x		x		x
Endpoint/Safety Assessments			x	x	x	x	x	x	x
Imaging		x					x		

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Example Personnel Budget

A - SENIOR/KEY PERSONNEL

	PREFIX	FIRST NAME	MIDDLE NAME	LAST NAME	SUFFIX	PROJECT ROLE	BASE SALARY	CAL. MNTHS	ACAD. MNTHS	SUM. MNTHS	REQ. SALARY	FRINGE	FUNDS REQ.
1		Suzy	Q	Research	PhD	PI	150,000	3.600			45,000	15,750	60,750
2		John	R	Advisor	MD, PhD	Co-investigator	186,600	0.600			3,330	3,266	12,596
3		John	A	Doc	PhD	Statistician	137,592	0.360			4,128	1,445	5,572
4		Jack	T	Surgeon	MD	Co-investigator	186,600	0.240			3,732	1,306	5,038
5													
6													
7													
8													
9	**Total Funds requested for all Senior Key Persons in the attached file**												83,356

Additional Senior Key Persons: Add attachment

B - OTHER PERSONNEL

# Personnel	PROJECT ROLE	CAL. MNTHS	ACAD. MNTHS	SUM. MNTHS	REQ. SALARY	FRINGE	FUNDS REQ.
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
1	Secretarial Clerical	1.200			3,525	1,128	4,653
1	Systems Manager	0.600			3,691	1,181	4,872
1	Research Assistant	3.000			11,250	3,600	14,850
1	Clinical Research Coordinator	3.000			11,250	3,600	14,850
4	Total Number Other Personnel					Total Other Personnel	39,225
						Total Salary, Wages and Fringe Benefits (A+B)	123,181

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Clinical Costs

- Costs for imaging, treatment, follow-up
  - if standard clinical practice, bill insurer/patient
  - if part is experimental, estimate incremental cost
    - example: additional pulse sequences
  - if experimental technique/application, **need cost**
    - examples: PET after treatment to assess treatment response, optical imaging for breast cancer detection
    - if no CPT-based charge, may need to negotiate
- Other tests & costs associated with clinical care
  - additional lab tests, examinations, visits, etc.

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Travel

- Team meetings
  - can be local or other
- Sites visits - qualification
  - if multiple sites
- Site visits - monitoring & auditing
  - if multiple sites
- Presentation of results at meetings
  - generally 1-2/yr for PI +/- 1 co-investigator
- DSMB Meetings

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Other Expenses

- Subject fees (recruitment)
- Animal care
- Use of specific instruments (time)
- Postage
- Advertising (subject recruitment)
- Monitoring
- Presentation
- Rent/utilities – IF not supported via indirects

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Subcontracts

- Used to engage services of another institution
  - may be university or commercial institution
  - site accrual, core service (path, data mgmt, stats)
- Overhead allowed on first $25K from sub site (i.e., double overhead, contractor & sub). Sub site overhead is direct cost on primary budget.
- Subcontract vs. consulting
  - if you only need a small amount of personnel time, a consulting agreement may be better
    - overhead at primary institution
    - no overhead or fringe at sub

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NIH Budget Development

- Allowable vs unallowable costs:
  - Per The Code of Federal Regulations (CFR) uniform guidance (Title 2, Subtitle A, Chapter II, Part 200) determine which of your budget items maybe: unallowable, potentially justifiable, and allowable.
  - https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title02/2cfr200_main_02.tpl
- Determine when to use Modular Budget versus R&R Budget Form (see https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/develop-your-budget.htm for guidance)
- Include the following costs: Personnel (including fringe benefits); Equipment; Travel; Patient Care; Trainee costs (stipends, fringe, tuition, fees); Animal costs; Outgoing Subawards; & Indirect costs (negotiated F&A rate)
- Note: NIH salary cap must be used for senior personnel, not all DHHS agencies use a salary cap

Budget Justification

- Absolutely critical component
  - if budget elements or length are poorly justified, expect to be cut!
- For EACH ITEM in budget, explain why it is needed to complete the proposed research
- Make sure to double-check for consistency with the actual budget
- Avoid “to be named” – TBN = to be cut

NIH Budget Development Continued

- Budget Justifications

  General guidelines for writing budget justifications:

  - Follow the order of categories in the detailed budget when building the budget justification and ensure that it conforms to the sponsor's requirements.
  - Detail any items that are typically considered "unallowable."
  - Detail anything that changes or impacts the costs, such as cost sharing, merit increases, or anything that impacts the indirect costs.
  - Describe any large year-to-year variations in budget.
  - Modular Budgets do not require the itemization of all budget categories – see NIH guidance

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Modular Budgets

- Many grants of < $250,000/yr in direct costs are eligible for submission of modular budget
- Request funds in modules of $25k, do not need an itemized budget
  - but may still need itemized budget for internal
- Detailed budget justification is still required

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Industry-Sponsored Budget Development

- Startup costs - must prod sponsors for more information and determine:
  - Estimated length of study – impacts IRB fees, pharmacy fees
  - Do feasibility analysis of protocol to determine if clinical services they are requesting are provided at site and if equipment is accessible.
  - Training of staff, record storage charges, budget negotiations
- Determine per subject or per visit costs (the contract will detail payment terms and may be negotiated)
- Estimate staff time based on protocol
- Obtain research and regular rates for clinical procedures and professional fees, lab fees, shipping costs, pharmacy fees, and facilities fees

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NIH vs Industry Budget Considerations

NIH:

- Allowable expenses are pre-determined
- Research rates are already set and pre-negotiated between institution and DHHS
- Protocol determines what clinical procedures will be billed as SOC and which as research. This must be applied across the board to all patients.

Industry:

- Expenses are negotiable
- Startup time can be drawn out extensively due to contract and/or budget negotiations – consider this when determining a standard "startup fee"
- Protocol should determine what clinical procedures will be billed as SOC and which as research. Sometimes industry sponsors may want to pick and choose what to pay for. Often times this is not allowable per institutional policy. Must negotiate to bill equitably to all patients.

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Final Advice

- Carefully prepare realistic budget
  - obvious “padding” may bias reviewers
  - but … make sure you include all needed costs
- Pay careful attention to budget justification
  - poorly justified budget elements or inconsistencies mean cuts
  - Excellent tool to check your process
- Work closely with research administration
- Goal should be to complete at least 1-2 weeks before institutional sign-off
  - allows you to focus on science towards end

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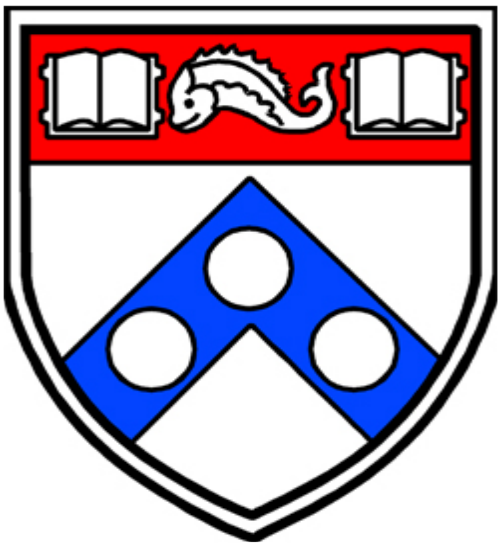

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