Day 1 - How to Have a Painless* Budget Meeting with Your Grant Administrator

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Ready, Set, Grant!

How to have a Painless* Budget Meeting with Your Grant Administrator
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Learning Objectives

• Understand key federal guidance and institutional policies that will affect budget development.
• Define key budget concepts and terminology.
• Evaluate the proposed project to identify resource and budgetary needs.
• Learn the importance of adequate budgeting at the proposal stage.
• Avoid the pitfalls of improper budgeting by being prepared.
Rules to Consider

• Federal Uniform Guidance:
  2 CFR 200 Subpart E – Cost Principles
• Federal awards will refer to Federal cost principles as guidance for determining costs that may be allocated to a project.
• To conform to 2CFR200, costs must be...
  Allowable
  Allocable
  Reasonable
Understanding Allowability

Criteria

• To be **allowable** the sponsor must allow AND the applicant’s institution’s policy/procedure must allow the expense.

• The expense must be able to be clearly **allocated** to a project for a specific project related purpose.

• The amount or proportion of the expense allocated to the project must be **reasonable** in proportion to the benefit the project will receive from that purchase.
Direct vs. Indirect (F&A) Costs

• Direct Costs
  • “costs that can be identified...with a particular sponsored project...or that can be directly assigned to activities relatively easily with a high degree of accuracy.” (A-21, D.1.)

• Indirect Costs (F&A)
  • “costs incurred for common or joint objectives and...cannot be identified readily and specifically with a particular sponsored project...or other activity.” (A-21, E.1)
Direct Cost Examples

• Direct Costs
  – Salary and Wages, Fringe Benefits
  – Express services, postage, large scale printing service necessary for project execution
  – Travel
  – Equipment
  – Specific Materials and Supplies required for a project
  – And more...
Indirect Cost (F&A) Examples

• Indirect Costs
  – Some Administrative salaries and wages
  – Routine express courier, postage, printing costs (submitting reports, photocopy)
  – Organizational memberships, books, subscriptions
  – Office Space
  – General and Office Supplies
  – And more...
OFFICE SUPPLIES
UNALLOWABLE
Facilities and Administrative Costs/Indirect Cost Rates

- Different types of projects have different F&A rates
- To Determine Which Rate to Use:
  - Look at your institution’s negotiated F&A rate agreement
  - What type of project is it?
  - Where is the work taking place?
- Rates are negotiated with the federal cognizant agency
  Classifications
  - Research, Training, or Other; On-Campus or Off-Campus
Sponsor-Limited F&A Rates

• A sponsor may only pay a certain percentage, or may not allow F&A at all
  • Must be in writing
  • Must be an actual policy that applies to all

• Examples:
  • NIH F31 Fellowships do not separately reimburse F&A
  • US Dept of Education limits F&A to 8%
VCU Policies to Keep in Mind

• Minimum Percent Effort Policy
• Cost Sharing
• Facilities and Administrative Cost Recovery
• Principal Investigator Eligibility
Minimum Effort for Key Personnel on Sponsored Programs

• PIs and Key Personnel must include some level of Committed Effort on most sponsored research activities
  – The minimum amount of effort committed to a sponsored research activity is 1% of the Key Personnel’s University Effort
Minimum Effort for Key Personnel on Sponsored Programs

• Exclusions
  – Equipment/Instrumentation grants
  – Mentor effort on dissertation, fellowship, & scholarship awards
  – Mentor effort on training grants
  – Specific purpose awards – travel grants, outreach programs, workshops, conferences
  – NIH Supplements – PI effort must be committed on the parent grant
Cost Sharing

• The portion of a project’s cost that is paid by the institution or another (non-sponsor) party

• When cost sharing is required for a particular program, PI must include the required committed cost share amounts in the proposal budget

• All committed cost sharing must be indicated and recorded in the RAMS SPOT cost share budget and on the Cost Share Authorization Form
Cost Share: Why Not?

• Cost Share Myths:
  – It will make proposals more competitive
    • Usually doesn’t unless sponsor specifies
  – It impacts reviewers’ funding decisions
    • They may not even see it!

• What Cost Share Really Does:
  – Lowers institution’s F&A recovery
  – Uses up scarce resources
  – Creates administrative burden
Facilities and Administrative Cost Recovery

• VCU will apply the full federally negotiated F&A cost rate or the sponsored published rate to proposals and agreements for all grants, contracts, and other agreements proposed and/or accepted, including those other agencies and instrumentalities of the Commonwealth.

• The following situations will NOT qualify as justification for less than including the full F&A rate in the proposal:
  – Sponsor limitation on total project cost
  – Price quotations with less than full F&A provided to a sponsor without approval of the Office of Sponsored Programs
PI Eligibility

• Sponsored Project PI required to be classified as a full-time employee of VCU or has accepted (in writing) an offer on a full-time basis. This may include:
  – President, Provost, Vice President, Teaching and Research Faculty, Term (non-tenure track) Faculty, Administrative and Professional Faculty

• Exceptions
  – A Pre- or Postdoctoral Scholar may serve as PI for a training grant when required by the sponsor
  – An individual with an appointment other than the above may be permitted to be a PI. Approval of the VP for Research and Innovation is required prior to proposal submission.
Now that you know the basics..
Conceptualizing the Budget

Preparing for that budget meeting......

Where do you start?

**Hint**

It is not about the numbers just yet, it is about your idea.
Before budget, we must have an idea and a plan!

Why are you writing a grant?

• You have an idea for a project
• You are developing a plan to execute your project
• But you need **funding** in order to do it!
Getting your ducks in a row

What do you need to get your idea funded?

• A good idea for a project.
• A clear plan on how you will execute your project.
• An agency who agrees it is a good idea and is willing to fund it.

A part of an agency’s willingness to fund an idea is a budget with reasonable cost in relation to the project to be conducted.
Finding a funding agency

Know the rules... read the guidance

- The Program Announcement (PA)
- Request for Proposal (RFP)
- Program Guidelines
- Agency website

Does your science fit within the mission of the sponsor and the funding announcement?
If the answer is no, find another avenue to fund your great idea!
Moving forward with budget

Know your project

You have to have a good understanding of what you are aiming to accomplish from a technical/scientific standpoint to be able to make a fair assessment of the budget it will take to complete the work.

We want to avoid this......

“It turns out we’ve only got enough money for R or D.”
A funding agency may fund work in your area. But that is not all that needs to be considered. The specifics of the funding mechanism must be explored:

- Can your project be completed within funding limitations or restrictions found within the program announcement?
- Look for specific restrictions/requirements
  - Budget caps, salary caps, no travel, no equipment, cost share required
- Look for specific allowances
  - Administrative costs, general equipment, renovations, travel allowance

Your administrator can help you navigate sponsor requirements, but they need information from you to do so.
Conceptualizing the Budget

Know your project....

- Plan the project, design the study, etc.
- Really think about the mechanics of HOW you execute the project:
  - Personnel, time, materials, space, travel, etc.
- Resources needed will then become more apparent.
- Identification of all resources needed to execute a project make estimating the cost simple and accurate.

Share your draft scope of work with your administrator prior to a budget meeting!
Conceptualizing the Budget

Know your project

1. Have a solid draft scope of work or project plan.
2. Share the plan with your administrator.
3. Prepare yourself to answer questions your administrator is likely to ask.
Conceptualizing the Budget

Consider the essential items you need to have in place in order to execute the project as proposed:

• People (personnel costs typically 70 – 80% of total budget)
  – PI, Co-I, other faculty
  – Staff
  – Students

• Subawards (contributing to scholarly/scientific conduct of project)

• Contractual Services (providing goods or services as a vendor at fixed rates)

• Materials/Supplies

• Equipment

• Travel

• Other (participant incentives, animal care, space/renovation, tuition)
Questions to Help Consider Cost

Personnel:

• What personnel are needed to do this work? (Roles)
  – Are there collaborators from outside your department?
  – Will sub-accounts for other schools/departments be needed? Is their administrator aware?
• What amount of time (effort) will be required on the project for each role identified?
• Who will manage the day-to-day activity on the project?
  – Should a project coordinator/director be included?
• Will a student be funded under this project? Can the program support stipend and tuition costs?
• Cost share considerations?

Identify personnel and their project roles prior to a budget meeting – This helps your administrator coordinate with other areas as needed.
Questions to Help Consider Cost

Collaborators:

• Will any external entity be involved in this project?
  – Will we need a **subaward** to another university to perform a specific aim or portion of the work proposed? Have effort levels been discussed?
  – Advisory group/Advisory boards – Will external individuals with subject matter expertise be contributing where **consultant** agreements are needed?
  – Are external entities needed to perform a specialized **contractual service** in support of this program? [sample analysis, translation services]

Your administrator will need a draft scope of work or services for each external collaborator and their contact information.
Questions to Help Consider Cost

Materials & Supplies:

Greatly dependent on the scope of your project

• Are you conducting bench research?
• Will lab work be performed by project staff “in house” (i.e. directly budgeted) or contracted out?
• Are you designing a community outreach or educational program?
• Will you be conducting a large scale survey?
• How are you collecting your data or samples?
• Will supplies be shared across projects? Are any supplies covered by cost share or in-kind resources from School/Department?
Questions to Help Consider Cost

Materials & Supplies:
Questions to Help Consider Cost

Materials & Supplies:
Questions to Help Consider Cost

Materials & Supplies:

Animal Research

• Is the IACUC protocol under development for submission?
• Costs of animals?
• Costs of maintenance and care?
Questions to Help Consider Cost

Other Costs:

• **Equipment** — Is new equipment needed to execute the project?

• **Travel** - Is travel an integral part of the project? Annual meeting attendance?

• **Other**
  – **Tuition** – are student stipends budgeted?
  – **Animal care** (types, quantities, length of time)
  – **Space** - Will new or renovated space be required to execute the project? Will you require clinical space?
  – **Service or maintenance fees** (associated with equipment maintenance)
  – **Administrative costs** (when allowable, for project with heightened administrative needs – program projects, contract, clinical trials)
So you want to perform clinical research or clinical trials...

I'M NOT ALWAYS ALLOWED TO DO CLINICAL RESEARCH

BUT WHEN I AM, YOU BET I'LL SCREW IT UP SOMEHOW
Clinical Research Definition

- Clinical Research per NIH
- [http://grants.nih.gov/grants/glossary.htm#C](http://grants.nih.gov/grants/glossary.htm#C)
- Research with human subjects that is:
  - 1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies.
  - 2) Epidemiological and behavioral studies.
  - 3) Outcomes research and health services research
  - Studies falling under 45 CFR 46.101(b) (4) (Exemption 4) are not considered clinical research by this definition.
Clinical Trial Definition

- Clinical Trial per NIH
  - A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.
Why Does it Matter?

• Research/Trial designation will impact required documentation
• If it is a clinical trial meeting certain criteria, you might be able to bill some items to insurance and not pay for it from your grant funds
• Your overhead rate may change
Know the Processes and Time points

• Institutional processes and requirements
  • Feasibility
  • Coverage analysis
  • IRB submissions
  • Conflict of Interest
  • Office of Sponsored Programs submissions
    • (RAMS-SPOT)

• Schools, Centers, Institutes processes
  • Any study involving cancer must be reviewed by the Protocol Review Meeting Committee (PRMC)
  • Most clinical research studies in the School of Medicine must have a complete feasibility assessment and conduct a Pre-Study Meeting
Is it feasible?

- Scientific Merit
- Institutional Resources
- Recruitment, Enrollment, and Retention
- Preliminary Financial Assessment
Key Documentation

- Protocol
- Coverage Analysis
- Informed Consent Documents
- Budget
- Contract (if applicable)
Coverage Analysis: What? & Why?

• **What?**
  • A focused review of all clinical trial related documents to determine financial responsibility for all items and services provided to the research participant over the course of the study.

• **Why?**
  • A complete coverage analysis creates a reference document for subsequent billing and invoicing decisions by study team, post-award team, and patient billing offices.
  • Maximizes your ability to use grant funds to cover necessary costs
  • Provides information that should be mirrored in consent documents and contracts
  • Essential documentation in the event of an audit

Reference: UCSF [http://hub.ucsf.edu/sites/hub.ucsf.edu/files/Coverage%20Analysis%20Matrix%20V.%201_total.pdf](http://hub.ucsf.edu/sites/hub.ucsf.edu/files/Coverage%20Analysis%20Matrix%20V.%201_total.pdf)
Importance of the Protocol

• Outlines goal(s) of the study
  • Supports determination of therapeutic intent
• Specifies how and when all necessary procedures, tests, exams, etc. will be performed
  • Necessary for Coverage Analysis and Budget
• Provides background and rationale for anticipated effects of the drug/device
  • Supports rationale for billing designations
Protocol: Key Considerations

• Write a Clean, Well-Developed Protocol
  • Awareness of the implications of listing specific locations, equipment, and service providers is critical
    • Things change
    • Changes trigger amendments
      • Amendments
        • Protocols are only modifiable by amendment (if already approved)
        • Amendments cost money
          • Regulatory Efforts for Submission
          • Additional work on the VCU IRB
          • Efforts to re-do coverage analyses and consent forms
    • Frustration for all parties involved
Protocol: Key Considerations

- **Samples**
  - How many assays really need to be conducted
  - Don’t forget about your control samples
  - Where are you going to store samples
  - Who has the ability to perform testing?
  - What tubes?
  - What tests?
  - Performed onsite or sent out?
  - Participant safety- amount of blood drawn?
Scenario

**Obstacle:** As written the protocol requires 100 participants according to the statistical analysis. PI admits that he typically treats approximately 20 patients per year.

- **Questions to Ask and Collaborative Solutions:**
  - Let’s check out your inclusion/exclusion criteria. Do you have flexibility to loosen the rigidity and still protect your participants and have the right population to evaluate?
    - Why?: Each Inclusion/Exclusion criteria should not put unnecessary restrictions on those included in the research. You want the data to be as generalizable as possible while protecting certain populations and ensuring you can answer the research question.
  - I am concerned about the grant timeline limitations since it will take you at least five years to collect the data. What if we look at a multi-site project and cultivate some relationships with either internal or external collaborators?
Scenario

**Obstacle:** Cost of potential project far surpasses the funding available in the grant due to several high cost procedures that the PI states are critical to their specific aims.

- **Collaborative Solutions:**
  - Discuss the possibility of alternative measurements/procedures that may be less costly
  - Is the project better suited for a different grant submission that may provide adequate funding?
  - Is the research being performed potentially a qualifying clinical trial or can it be redesigned as such?
  - Are all of the procedures necessary? Or are they just nice to have?
  - If you need initial data for a second project can you perform both aims on this project? Or can you go with the cheapest test to get initial data to support potential follow up projects?
Budget: General Concepts for Clinical Research

- Derives from the protocol and coverage analysis
- Coverage analysis and budget should be mirror images
- Includes:
  - Per participant costs
  - Start up Efforts
  - Ongoing Efforts
  - Closeout Efforts
  - Efforts for unpredictable events that may arise over the duration of the project (In industry budgets referred to as Invoiceable Items)
Requesting Prices for Clinical Services

- Will hospital clinic space or ancillary clinical services (e.g. Radiology, Clinical Pathology, Endoscopy)?
  - REDCap Request Process at VCU

- Some departments will provide pricing “quotes” at the time of a proposal, but also **require** the actual protocol to be submitted at the time of an award
  - Many times the scope of projects and protocols change
  - Some departments will support you in finding solutions to improve your study design to try to work with your level of funding (e.g. CRSU)

- Investigational Pharmacy has a separate pricing request link. Investigational drugs must be stored in specific locations
  - At VCU Investigational Drug Services must store your investigational product, unless a waiver is approved.
  - Why?:
    - Temperature controls
    - Blinding
    - Compliant and sterile preparation
Other Considerations
Participant Compensation or Stipend

- Should not be coercive
- Budget negotiators should include this cost in budget development
- Some institutions have moved towards not paying participants

**Budget**
- Should cover amount of participant compensation

**Informed Consent Documents**
- Should delineate compensation
Other Clinical Research Components

• No Cost Items and Services “Free”
• Investigator Held IND/IDE
• Clinicaltrials.gov registration/reporting
Preparing for that budget meeting......

- When should you meet, and what should you bring?
- What is your role, and what will the Grants Administrator handle?
- How will we get it all done, and how long will it take?
Pre-Meeting Considerations

– The Grants Administrator works with a large number of faculty, in a number of different roles. Make an appointment to meet with them sooner rather than later! You never know how many of your colleagues are applying for the same opportunity, or share the same deadline as you.

– Send the Program Announcement and Funding Opportunity to the Grants Administrator ahead of time so they have a chance to read it over prior to the meeting.

– Document any questions you have regarding the Program Announcement/Funding Opportunity, so the meeting can be as organized and productive as possible.

– Gather together and Organize anything you already have in regards to the budget. For example, if you know you’ll be working with outside University personnel, bring their contact info for the Grants Administrator so those conversations can start right away.
When Should You Meet?
Consider that there are a number of Deadlines in play:

- Funding Sponsor Deadline...
- The Sponsored Programs Deadline...
- Your School/Dean Deadline...

Which all come AFTER your Grant Administrator’s Deadline
# Who Does What?

<table>
<thead>
<tr>
<th>Task</th>
<th>PI</th>
<th>Grant Administrator</th>
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</thead>
<tbody>
<tr>
<td>Review the program/funding announcement prior to the meeting and make notes</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Review the Scope of Work/Abstract to understand what personnel, space, and other resources may be needed and should be budgeted for</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Help format, calculate, apply rules and regulations, create and polish up the budget forms</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Guide PIs in the right direction to request funds in manner that avoids post award management issues</td>
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<td>X</td>
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<tr>
<td>Plan the project, design the study, etc.</td>
<td>X</td>
<td></td>
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<tr>
<td>Consider the mechanics of HOW to execute the project that has been designed.</td>
<td>X</td>
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What to Bring?

DO Bring:
• A Scope of Work/Abstract
• Your Layman’s Pitch
• Any and all supporting documentation (subaward contact info and internal budget for their needs, pricing from ancillary departments, equipment price quotes)
• A Calendar
• Coffee and a Smile
• An understanding that you and me may not speak the same “language”

Please leave at home:
• Invoices and receipts for things you’ve already purchased as “pre-award” costs
• Dollar amounts listed on cocktail napkins
• Your mentor’s NIH budget pages from 1997
• Your checkbook
TEAM WORK!!!!
Once the budget is drafted, it is time to divide and conquer!
Ready, Set, SCHEDULE

• Decide who does what for the proposal, and make sure it is clear and deadlines are in place

• Schedule Follow-Up Meetings to pull together the proposal as it is being worked on by both the PI and the Grant Administrator

• The Grant Administrator should document the meeting discussion and the decisions made and pending assignments via email and send out all calendar requests as needed
Ready, Set, SCHEDULE

And of course...everyone should breathe a sigh of relief, smile, and high 5 for a job well done!
Keys to Success
Be Realistic and Proactive!

• Projects always take longer than expected
• Projects always cost more than expected
  – You will save...
    • Time
    • Money
    • Frustration
  – And...
    • INCREASE YOUR CHANCE OF GETTING FUNDED!
At the risk of sounding cliché...

“IT TAKES A VILLAGE”
Collaboration: Critical to Avoid Fights and Fires
Learning Objectives

• Understand key federal guidance and institutional policies that will affect budget development.
• Define key budget concepts and terminology.
• Evaluate the proposed project to identify resource and budgetary needs.
• Learn the importance of adequate budgeting at the proposal stage.
• Avoid the pitfalls of improper budgeting by being prepared.
QUESTIONS
VCU Policy Links

• VCU Office of Research and Innovation Policies and Procedures
  – http://www.research.vcu.edu/policies/index.htm

• Federal Uniform Guidance Implementation at VCU
  – http://www.research.vcu.edu/osp/policies.htm
Investigator Held IND/IDE

• 21 CFR Part 312 Investigational New Drug Application

• 21 CFR Part 812 Investigational Device Exemptions

• 21 CFR Part 50 Protection of Human Subjects

VCU investigators should contact INDIDE@vcuhealth.org for more information and to learn about specific requirements.

VCU IND/IDE Website: [http://www.research.vcu.edu/IND_IDE/](http://www.research.vcu.edu/IND_IDE/)
Never developed a budget for a clinical research project?

• Locate institutional resources
  – At VCU contact Clinical Research Services
    • crsbudgets@vcu.edu

• Talk to your financial administrator

• Talk to your Dean’s Office
Clinical Research Budgeting: Helpful Links

• Research Administration Wiki Pages
  • go.vcu.edu/ccra
  • CRS Budgeting Best Practices Cost Consideration Guide

• School of Medicine Website
  • [http://www.medschool.vcu.edu/about/finance/researchadmin/administrators/bestpractice/proposalbudget/](http://www.medschool.vcu.edu/about/finance/researchadmin/administrators/bestpractice/proposalbudget/)