



# Creating a Budget for Individual Research

Kathryn I. Pyle, AMLS, MA, Medical Informatics  
& Clinical Epidemiology

Bridget Adams, MSHS, CCRA, OCTRI

Neil Unger, Office of Proposal and Award  
Management

OCTRI Research Forum      February 24, 2015



# Today's talk



- A. General guidelines in budget preparation: Kathryn Pyle
- B. Preparing a clinical trial budget: Bridget Adams
- C. Budget review by Office of Proposal and Award Management: Neil Unger

# A budget is an important part of preparing a research proposal.



The budget provides a financial blueprint for your project and shows that you will manage the sponsor's funds responsibly.

# First of all, carefully read the Funding Opportunity Announcement for budget information.



Are there limits to the funding?

Total costs?

Total direct costs?

Salaries?

Personnel allowed on the project?

F&A rate?

Identify all the costs that are *necessary* and *reasonable* to complete the work described in your proposal.

Reviewers look for reasonable costs and will judge whether your request is justified by your aims and methods.



Reviewers will consider the person months you've listed for each of the senior/key personnel and will judge whether the figures are in sync with reviewer expectations, based on the research proposed.

# Is your budget appropriate for your project?

Costs charged to federal grants must be:

Allowable  
&  
Allocable  
Reasonable

Some budget items are not allowed at an institutional level – they are supposed to come out of indirect costs.

From Uniform Administrative Requirements, Cost Principles  
and Audit Requirements for Federal Awards

Planning a budget early can help to determine if you can afford your research project.



I like to create a budget in Excel first and then tweak it to create a final version before loading into electronic forms.

In many types of research, personnel are usually 80-90% of your budget.



Who are key personnel?

How much FTE (calendar months) should each investigator or staff have to conduct the study?

Are there any personnel requirements in the RFA?

Is there a maximum or minimum FTE restriction for the PI?

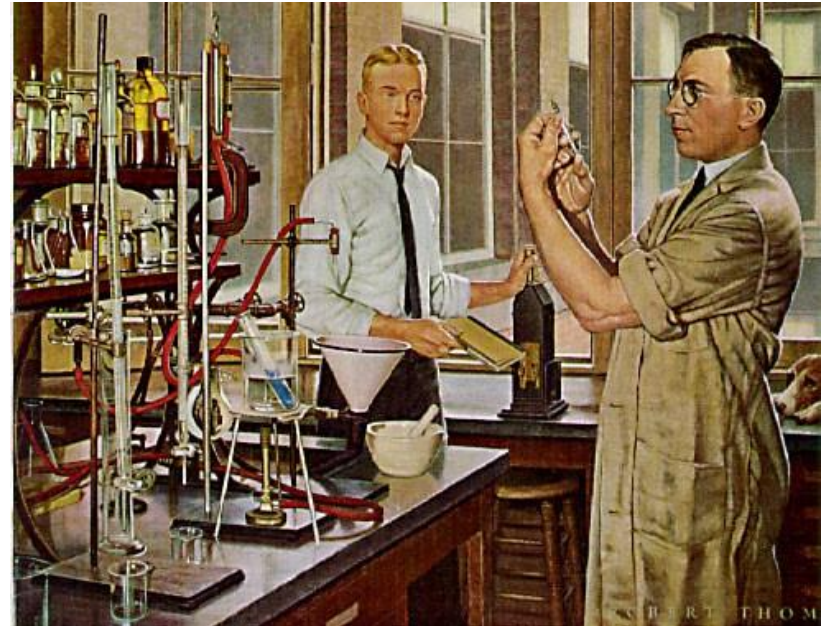
Are some kinds of personnel not allowed on the project?

# Determine who your co-investigators are.

How will they contribute to the research?

Make sure they have enough FTE to devote to the project.

If they are from another department, make sure there is buy-in from that department and that you have correct salary information.



# Decide on your non-key personnel.

What research personnel do you need?

These are often To Be Determined or To Be Named.

If so, work with your departmental grants coordinator to make sure you are using appropriate salaries in your budget.

Can some services be supplied from OHSU Shared Resources? These would be fee-for-service and not personnel costs.

Example: OCTRI statisticians



Other significant contributors do not have measurable FTE on a project.

Individuals who commit to contribute to the scientific development or execution of the project, but do not commit any specified measurable effort (i.e., person months) to the project. These individuals are typically presented at effort of “zero person months” or "as needed." Individuals with measurable effort may not be listed as Other Significant Contributors (OSCs).



NIH doesn't prohibit an assumed 3% annual merit increase built into each year of a grant proposal.

# In 2015, the NIH salary cap is \$183,300.

This salary level is used by other DHHS agencies, for example, AHRQ.

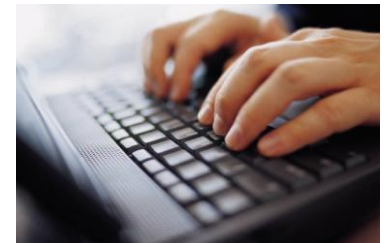
If someone is at or above the cap, use that level as the full-time equivalent salary for all years of a proposal budget.



# Determine non-labor expenses.

Non-labor expenses are usually minimal for non-clinical trials.

- Travel to required meetings and/or scientific meetings to present research results
- Inter-Library Loan costs to obtain journal articles
- Teleconferencing
- Publication costs
- Consultants
- Laptop computers dedicated to the project
- Software such as statistical or reference management
- Lab supplies



# Consultants are a “briefcase and a brain.”

An individual who provides professional advice or services for a fee, but typically not as an employee of the engaging party. OHSU employees cannot be consultants – you need to list them as personnel with salary and FTE.

If you are listing a consultant from another institution, make sure s/he is able to be a consultant, that the other institution will allow that and not require a subaward.

While the NIH salary cap does not apply to consultant fees, the rate used should be reasonable and justifiable.



# Travel costs are separated by domestic and foreign travel.



Travel costs may be requested for field work, attendance at meetings

and/or conferences that are either necessary to accomplish proposal objectives or where results of the proposed research are presented, and other travel associated with the work proposed.

For NIH, all air travel paid for with federal grant funds must be on a U.S.-flagged carrier if available.

# Equipment is its own budget category.



OHSU definition: Tangible, nonexpendable personal property having a useful life of more than one year and an acquisition cost of \$3,000 or more per unit.

Computers are considered equipment only if each unit is \$3,000 or more AND that cost is directly applicable to the project. Otherwise, it is considered a supply.

Supplies are tangible items used to conduct the research.

When charged as direct costs, materials and supplies must be



directly allocable to the research project: things such as chemicals, test kits, laboratory glassware and small equipment, specialized software packages or licenses, specimen bottles, or anything else that you need to carry out the research you are proposing.

OHSU does not allow “general office supplies” as a budget item on grant applications.

# You can budget for incentive payments to study participants.



"Anyone for a game of Blind Man's Bluff after dinner?"

Incentive payments to volunteers or patients participating in a grant-supported project or program are allowable. Incentive payments to individuals to motivate them to take advantage of grant-supported health care or other services are allowable if within the scope of an approved project.

Other costs is a miscellaneous category.

Publication costs: NIH allows costs for dissemination of research findings from the proposed research. These would be costs in later years of the grant.

Teleconferencing: if you need to communicate with agency personnel or subcontractors

Fee-for-service costs: such as OHSU Shared Resources

Note: Food and entertainment costs are not allowed on NIH grants.



Subcontract or subaward expenses are a special part of a grant budget.



Subcontract direct and indirect expenses are considered part of the prime institution's direct expenses, but subcontract indirects are not considered if there is a maximum allowed for direct costs. Many institutions take indirects costs on the first \$25,000 of a subcontract budget.

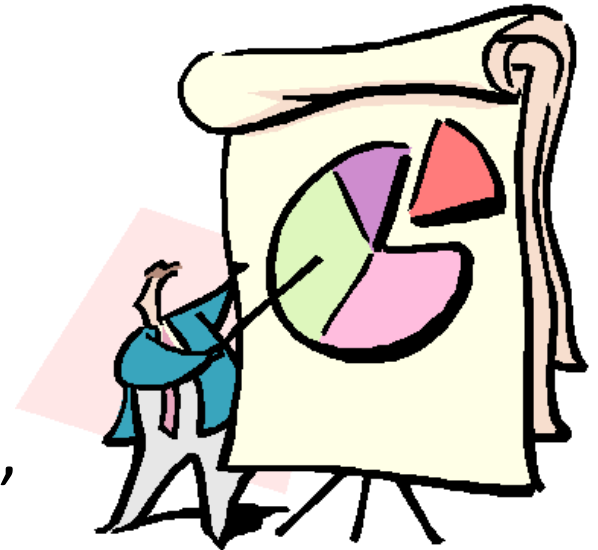
# Make sure your budget justification will answer any questions reviewers may have about your budget.

Personnel section should indicate what each person will be doing on the project.

Provide detail for travel, consultants, other direct costs (unless modular).

Subcontract costs need a justification as well.

Explain increases or decreases per year.



NIH grants with direct costs that average no more than \$250,000 over all years are submitted as modular budgets.

This can be done for certain R grants and is a simplified method.

But you still need to create a detailed budget for yourself and your institution.

AHRQ does not have modular budgets, nor does PCORI.



# Be aware of direct costs vs. indirect costs.

Direct Costs: Costs that can be identified specifically with a particular sponsored project, an instructional activity, or any other institutional activity, or that can be directly assigned to such activities relatively easily with a high degree of accuracy.

F&A Costs: Costs that are incurred by a grantee for common or joint objectives and that, therefore, cannot be identified specifically with a particular project or program. These costs also are known as “indirect costs.”

NIH usually has a limit on direct costs while AHRQ has a limit on total costs.

The PA or RFA will tell you of any budget caps.

For NIH grants, you normally need advance permission to exceed \$500,000 per year of direct costs.

AHRQ usually puts a cap on total costs, both directs and indirects (F&A).



# NIAID is a great resource for investigators.

National Institute of Allergy and Infectious Diseases has All About Grants Tutorials.



National Institute  
of Allergy and  
Infectious Diseases

[www.niaid.nih.gov/researchfunding/grant/pages/aag.aspx](http://www.niaid.nih.gov/researchfunding/grant/pages/aag.aspx)

There is a section on budgets:

"Strategy for NIH Funding: Plan Your Budget":

<http://www.niaid.nih.gov/researchfunding/grant/strategy/pages/3forms.aspx#j01>

# In conclusion

Working early to identify all the components of your proposal budget and verifying that your budget meets proposal requirements can lead to a successful proposal budgeting experience.





# Budgeting for Clinical Trials

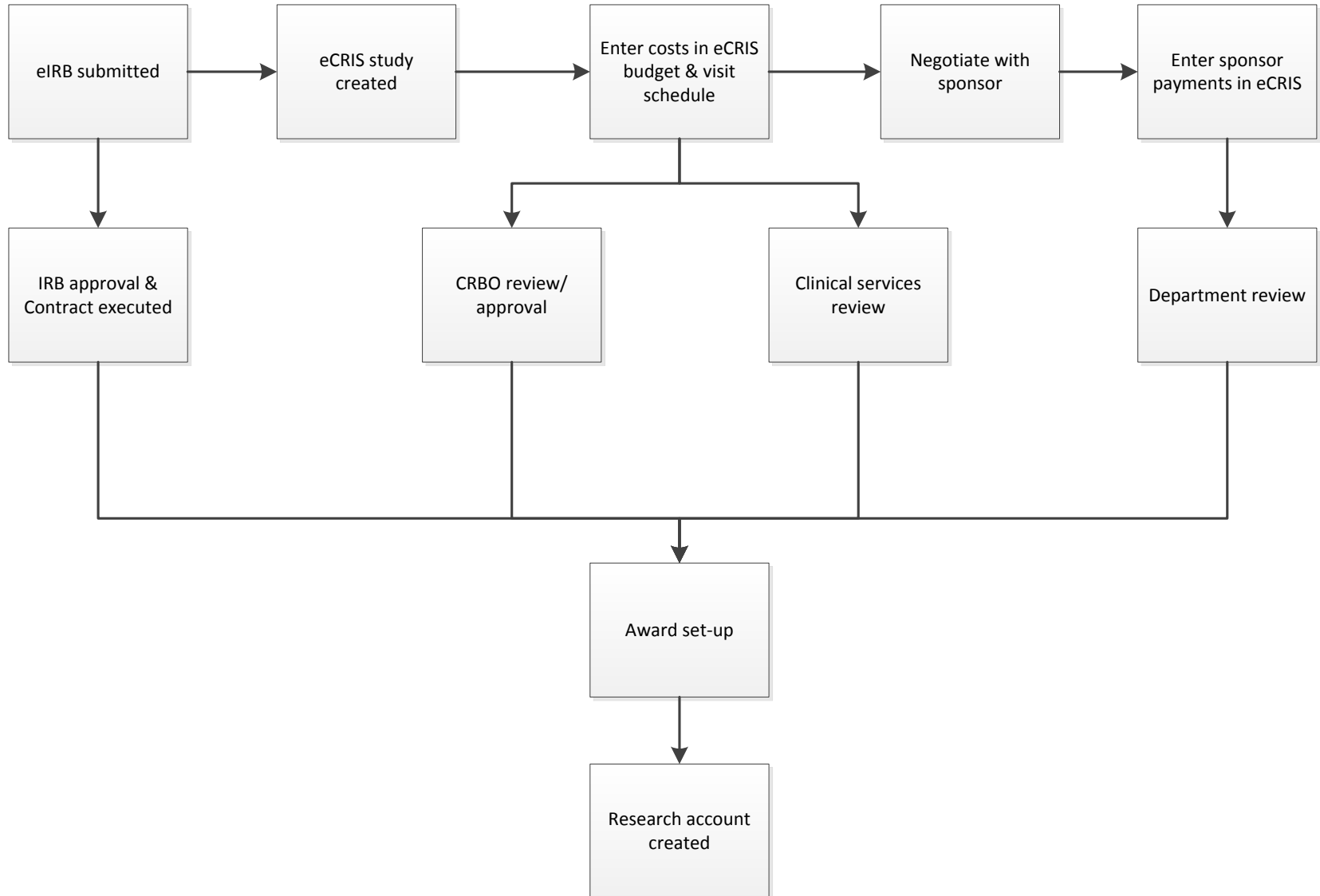
**Bridget Adams, MSHS, CCRA, Manager**

Investigator Support & Integration Services (ISIS),  
Oregon Clinical & Translational Research Institute (OCTRI)

# What is a Clinical Trial at OHSU?

- Clinical Drug/Device Investigation
  - Mission code 54
  - A study of a drug (device, or diagnostic) where it “...is administered or dispensed to, or used involving, one or more human subjects.” and is a "prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical...interventions (drugs,... devices, or new ways of using known drugs...or devices).”
  - Translation: A drug or device intervention into a person

# Industry Budget Process Overview



# Grant Budget Process Overview



# eCRIS

- **Electronic Clinical Research Information System (eCRIS)**
- Institution-wide computer application for budgeting, financial management, contracting, and study management, including subject tracking, regulatory reporting and document management, of OHSU clinical research studies.

# Budget Preparation

- **Analyze Costs**

- Identify standard of care vs. research procedures at OHSU

- Don't rely on the industry sponsor or coordinating center tell you what is standard – it can vary
    - This should be done by the PI or MD-Col
    - Questions about what you can/can't bill to insurance ask the Clinical Research Billing Office (CRBO)

# Budget Preparation

- **Determine Rates**
- **Hospital Services**
  - Obtain rates from Clinical Department Contact, eCRIS (industry) or Research Rates Database (non-industry)
  - **Technical Fees**
    - Federal: Must use research rate (Hospital price X Research Rate % = Research price)
    - Industry sponsored: Budget for full price if possible
      - » Will be charged research price (see below)
    - Budget for ~10% increase per year
  - **Professional Fees**
    - Standard discount (\$75/RVU) reflected in database
    - Invoice from UMG reflects discount

# Budget Preparation

- **Determine Rates (cont'd)**
- **University Services**
  - Service Center Rate
  - Contact Manager of Service Center
- **Outside Vendors**
  - Commercial vendor services: Agreement through logistics
  - Outside organization involved in the study: Subcontract

# Budget Preparation

- **Build Budget**
- **Industry sponsored**
  - Build budget and visit schedule in eCRIS
  - Enter all costs, regardless of sponsor's proposed budget
  - Enter proposed sponsor payments in eCRIS budget smartforms
  - Negotiate higher sponsor budget than costs

# Budget Preparation

- **Apply Correct Indirect Cost Rate (IDC)**
  - Industry:** 25% Total Cost (TC)
    - 20% institutional F&A
    - 5% Department Assessment (DA)
      - Some departments don't assess, stays in account
      - Some departments assess more, add line item in sponsor budget
      - Some divisions assess in addition to department assessment, add line item in sponsor budget
    - IDC and DA, if applicable, automatically applied in eCRIS
  - Non-industry:** 32% Modified Total Direct Cost (MTDC), excludes:
    - Patient care costs
    - Equipment
    - Tuition, etc.

# Negotiating Budget

Minimum: all research costs must be covered in budget

- All tests and procedures
- Salary support (investigator, study coordinator, other)
- Professional fees (if not already getting salary support)
- Other invoicable costs (informed consent translation, IRB initial, continuing, and modification review fees\*, pharmacy\*\*, shipping, document storage, subject reimbursement, supplies, advertising, etc.)

\*Required if industry sponsored    \*\*Required if study of drug

# Unallowable Costs

- Industry
  - Finders fees
  - Referral fees
  - Enrollment incentives
- Federal
  - All industry unallowable above
  - Also unallowable costs per A-21
    - Administrative
    - Preparatory to research , etc.

# Clinical Trial Financial Resources

- Clinical Research Billing Compliance Office (CRBO):  
<http://www.ohsu.edu/xd/research/about/integrity/crbo/index.cfm>
- OPAM Clinical Trials Policies and Procedures:  
<http://www.ohsu.edu/xd/research/administration/sponsored-projects-administration/policies-procedures/clinical-trials.cfm>
- OCTRI Forms & Policies:  
<http://www.ohsu.edu/xd/research/centers-institutes/octri/resources/policies-forms/index.cfm>
- eCRIS Website: <https://o2.ohsu.edu/ecris/>



# OPAM Review of Application Budgets

**Neil Unger, Grants and Contracts Administrator**

Office of Proposal & Award Management

# What do the GCA's in OPAM do?

- The majority of our time is spent assisting PI's and administrators in the application submission process.
  - We stay up to date on Federal and University guidance
  - We provide feedback on the guidelines related to formatting, budgeting, and sponsor requirements
  - We review applications to insure compliance is being met, and that the application submitted follows as closely as possible the instructions set out by the sponsor.

## REGARDING BUDGETING...

-It is the obligation of the PI and admin to create a budget with costs that are *necessary* and *reasonable* to complete the work described in your proposal.

OPAM doesn't review this aspect, as we are not scientists!

-It is also the obligation of the PI and admin to attempt to budget costs that meet the guidelines of the sponsor's instructions.

OPAM does review for this aspect.

## REGARDING BUDGET RULES...

- Everything starts with the Sponsor's specific funding opportunity which you are applying for.
- R's, K's, F's, T's and other opportunities all carry unique guidance regarding allowability.
- More general overall instructions from the sponsor are still in effect where applicable, unless otherwise changed in the FO.

## REGARDING BUDGET ITEMS...

For Personnel, we look to make sure:

- The salary listed in the budget meets the person's actual level
- No personnel are above the NIH salary cap (\$183,300 today)
- Annual Increases for personnel are no more than 3% annually
- Post Docs and Grad Students are at stated stipend levels\*
- Calendar months and personnel count are entered correctly

These items are applicable to key, non-key, and sub award personnel.

\*Current Stipend levels listed in NOT-OD-15-048

## REGARDING BUDGET ITEMS...

### Additional Personnel Considerations:

- Are Mentors included?
- Is there a specific effort percentage the PI is required to commit?
- Are fringe rates figured correctly?
- Is Cost-Sharing required, and entered correctly if so?
- Are personnel listed as Key done so correctly?
- Are Consultants listed correctly?

## REGARDING BUDGET ITEMS...

### Non-Personnel Considerations:

- If it is a detailed budget, are the items broken out line-by-line
- Are the items that affect the F&A base, such as equipment and patient care, listed correctly.
- Is the F&A rate for the subcontract correct?
- Is the F&A rate for OHSU correct, per terms of the FO?
- If a Modular budget, has the correct number of modules been entered?

## REGARDING BUDGET ITEMS...

### Specific to the Budget Justification(s):

- Is the information on the Budget Justification correct per the budgeting method (Modular vs Detailed)?
- Does the budget justification information match the budget?
- Has the Budget Justification for OHSU and the proposed subawardee been loaded in the correct place?
- Is there a need for an Additional Narrative Justification?

# A simplified approach

- A budget starts with what you need to accomplish the proposed project. Work with your department and other scientific resources to understand this information.
- Locate a funding source that would work well to support this project. RDA is available to assist with this.
- Read the stipulations of the funding opportunity, and try to become familiar with the sponsor's general guidelines.
- Ask a GCA! We are here to help you get the budgets right, and to make sure your application meets its potential.