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"Happy Trials to You"

Introduction to Budget Development for NIH Grants By Jenna Lee

Developing a clinical research project budget for a National Institutes of Health (NIH) funding proposal can be a daunting task. There are numerous factors to consider: How long will the project take? How many people are required? What types of supplies will be required? Will travel be involved? Do the costs comply with all the federal rules and regulations? This article will discuss these factors and many other considerations in developing a budget for an NIH grant proposal.

The Basics

Formulating an NIH budget boils down to two major principles: (1) the scientific requirements should drive your budget and (2) compliance is essential.

Consider these objectives as you begin to outline your budget:

- **Get the numbers right.** As you think about the project you are proposing, understand exactly how much funding is needed to complete the work. This is a good first step before you actually begin to complete the NIH forms. Accurately estimate the cost of the project. Living within an inadequate budget is difficult, and the NIH will not give you more money just because the project runs over budget. "Bargain science" is noticeable. On the other hand, overestimating costs offers the NIH poor value for its limited funds and gives the appearance that the budget has been padded or poorly conceived.
- **Estimate future costs carefully.** In the past, it was acceptable to ask for a 3% increase in each budget year. In fiscal year 2012, however, NIH reversed this policy because of decreased funding levels. Special increases for equipment or personnel are still allowed with justification.
- **Justify unusual costs.** Your project may call for an unusual or "large ticket" item. For example, you might need a piece of equipment in Year 1 to start the project. Such costs are acceptable but must be clearly justified.

The Office of Management and Budget's (OMB) Circular A-21 (2 CFR, Part 220) clearly outlines federal regulations on how grant money can be used. The following high-level principles outline how to think about costs when using federal grant dollars:

- Reasonable. Reasonable costs are those goods or services acquired where the
 amount involved reflects an action a prudent person would have taken. An
 objective outsider should agree that these costs are appropriate to the
 circumstances.
- **Allowable.** Allowable expenses are those that are not expressly prohibited by the funding agency or the specific grant announcement.
- **Allocable.** Expenses must benefit the project. It must be evident, for example, that you are utilizing the requested lab supplies for this particular project and not, for example, some other NIH project.
- **Consistent.** Similar costs incurred in like circumstances must be treated consistently.

Detailed Budgets

NIH budgets allow costs in the following main categories:

- **Personnel.** Determine the roles, numbers and qualifications of personnel, including yourself, who will work directly on the project (and not in capacities covered by overhead see below). Then, determine the percentage of time (effort) each person will spend on the project, e.g., 10%, 50% or 100%. Be realistic about what each individual can accomplish in the specified time. The NIH uses the following categories for personnel:
 - **Senior/Key Personnel.** These are the senior personnel from your organization, including the Principal Investigator. These people are essential to completing the project and are committing measurable time to the research.
 - Other Significant Contributors. These are people who provide some type of overall leadership or supervision, e.g., mentoring, but their effort is negligible. They do not have to be employees of your organization.
 - **Consultants.** Consultants are personnel who are not employed by your institution, including full-time contractors.
 - **Other Personnel.** These employees can be listed by role, rather than by name. For example, you may need two study nurses to work on your project. These personnel can be listed as:

Study Nurses - 2 - \$60,000 each - \$120,000

The Department of Health and Human Service's (DHHS's) current legislative salary limitation caps annual compensation at \$179,700 per individual. Therefore, if an individual is committing 50% of his or her effort to the project, the most you can budget for is \$89,850 (assuming his or her actual salary is at least \$179,700).

Clerical and administrative staff time is typically considered part of your administrative costs that are covered by your institution's Facilities and Administrative (F&A) cost rate. While the government has specified exceptions to this policy, you should confer with your grants administrator to discuss allowability before including these types of costs in your budget.

- **Equipment.** If you need new equipment, specify it. Equipment should be project-specific and must be justified in the budget. A piece of equipment costing over \$5,000 usually qualifies as a "big ticket item" that must be listed separately and should be well justified. Most equipment is requested for the first year of a project. If you are utilizing the modular budget format, you may add another module(s) to cover equipment.
- **Travel.** Travel funds are typically small, usually about \$1,000-\$2,000 per project meeting or conference (e.g., to present project results), per individual, per year. Grants typically support one meeting per year for two to three individuals. In the application, explain how the travel directly relates to the research.
- **Materials, supplies and services.** Consider what other materials, supplies and services you may require, such as lab materials, shipping and publication fees. Also identify institutional services, such as shared equipment or facilities that are subject to standard internal charges.
- **Subaward (consortium) costs**. These are charges by other institutions for performing a portion of the project. A subaward budget looks like a regular budget and is submitted to the NIH along with the main budget.

Once you have appropriately drafted estimates for the categories above, you must justify why you need the amounts requested. It is important to estimate the materials and supplies needed for the personnel involved with the project. It may be reasonable to estimate a supply budget of about \$10,000-\$15,000/year for each full-time equivalent (FTE) person on the project. The actual amount, however, depends on the nature of the research proposed. For example, the supply costs for a clinical trial will be much higher than those required for a project that utilizes computer simulations rather than human subjects.

Subawards

The federal government makes a distinction between "subawards" and "procurement contracts." A procurement contract might cover the cost of 20 CT scans, while a subaward might cover the cost of enrolling and managing five study subjects at a different institution. OMB Circular A-133 outlines five distinct characteristics of each:

- Subawards:
 - The subrecipient determines how it uses its own budget.
 - The subrecipient's performance is measured against the objectives of the grant.
 - The subrecipient has responsibility for programmatic decision-making.
 - The subrecipient has responsibility for adherence to applicable federal program compliance requirements.
 - The subrecipient uses the federal funds to carry out a program, as opposed to providing goods or services for the pass-through entity.
- Procurement contracts:
 - The contractor provides goods or services within normal business operations.
 - The contractor provides similar goods or services to many different purchasers.
 - The contractor operates in a competitive environment.
 - The contractor provides goods or services that are necessary for the operation of the federal program.
 - The contractor is not subject to compliance requirements of the federal program.

Modular Budgets

Modular budgets are the NIH's way of simplifying the budget process for certain grants. Institutions should still attempt to project costs accurately, but not to the level of detail required by regular budgets, which are commonly referred to as "detailed budgets." (See above.)

Modules are in increments of \$25,000, i.e., \$25,000, \$50,000, \$75,000, etc., up to a maximum of \$250,000 of direct costs per year. Instead of breaking out a detailed budget as described above, lump project costs into Total Direct Costs, Total Indirect Costs, and then Total Costs.

An easy way to determine the amount of each module is to calculate the total direct costs you need overall for the project and divide that amount by the number of years in the project. Then, round that number up to the nearest \$25,000 increment. For example, if you estimate that your research costs will be approximately \$130,000 per year, it is acceptable to round up to \$150,000. Set each of your modules at that amount, e.g., \$150,000 in direct costs per year. However, if the cost varies significantly for any particular year, e.g., to pay for equipment, the module for that year can be higher (or lower).

Like detailed budgets, modular budgets include personnel names, effort, role on the project, and pertinent experience, but salary information is not required.

Subaward costs are the one line item that must be listed separately in each module. (Do not break out equipment and other one-time costs, but explain them in the justification section.) In the main budget, estimate each subaward's total costs (including indirect costs) for each year, rounded to the nearest \$1,000. List the subaward organizations (and individuals) along with all of their personnel (including person-months) and roles on the project; however, do not list individual salary information.

Patient Care Costs

In NIH budgets, the costs of healthcare services provided to research subjects are called "Research Patient Care Costs." NIH-sponsored research may pay for such costs that are beyond standard of care. If you are going to include these types of costs in the budget, list the names of any hospitals or clinics and the costs associated with each. Also include the research costs for each patient (including number of days in treatment and the cost of each test or treatment), provided they would not have received such services but for their participation in the research study. Inappropriately charging the grant for Patient Care Costs is subject to severe federal fines and penalties for the institution and principal investigator.

Some patient costs do not constitute Patient Care Costs for NIH budgeting purposes but may still be allowable by the NIH. Such costs include reimbursement to the patient for travel and gene sequencing performed in facilities outside the recipient organization on a fee-for-service basis. Categorize these costs as Other Costs, rather than Patient Care Costs.

Cost Sharing

Consider cost sharing when creating the budget. "Cost sharing" is the portion of the project that is paid by the institution, not the NIH. There are two types of cost sharing:

- Mandatory. This is the portion of the institution's contribution to the project
 costs that is required by the terms of the program announcement. It must be
 described in the budget or a proposal will receive no consideration. The NIH
 rarely requests cost sharing as a condition of receiving a grant. Nevertheless,
 statutory salary limits are a form of mandatory cost sharing.
- **Voluntary.** This is the portion of the institution's contribution to the project costs that is not required by the sponsor. The institution freely offers it. It could be in the form of unpaid effort by a member of the project team or some other in-kind service being provided on the project. Should the proposal be awarded with voluntary cost sharing, the actual amounts must be tracked and reported properly.

Conclusion

At most research institutions, about 30% of all submitted proposals are actually funded by the sponsor (both federal and non-federal). In 2011, the success rate for new NIH awards was only 15.2%. Therefore, it is important to submit scientifically compelling proposals at competitive prices, with clear explanations and justifications. Proposals must also include budgets acceptable to the institution.

Author

Jenna Lee is a Manager at Huron Consulting Group. Contact her at 1.312.823.8381 or jlee@huronconsultinggroup.com.