

Grant Development for Large Scale Research Proposals: An Overview and Case Study

Ira S. Goodman

Associate Director for Administration
Moores Cancer Center
University of California, San Diego
3855 Health Sciences Drive
La Jolla, California 92093
Tel: (858) 822-1221
Email: igoodman@ucsd.edu

Author's Note

The opinions and conclusions in this paper are those of the author and do not reflect the policies or position of the Moores Cancer Center or the University of California San Diego (UCSD). Appreciation is expressed to the highly skilled Moores Cancer Center administrative team participating in the grant development process.

Abstract

With some NIH pay lines running at or below the 10th percentile, and funding becoming scarce for large science grants, new approaches are necessary to secure large interdisciplinary grant awards. The UCSD Moores Cancer Center has developed a team approach, starting with the identification of a competitive opportunity and progressing to the designation of a project team of faculty and administrators through to the submission of a finely tuned product. An important aspect of this approach is that scientists and administrators are on an equal footing, bringing to the table unique skill sets and experience critical to the process. While every application will not be successful, the effort will not fail from an apparent absence of expertise, diligence, or awareness. Grant development will be a more critical area of research administration as competition for limited funds increases.

Keywords: interdisciplinary, grant development, research administration

Introduction

The NIH, with a 2010 budget of \$31 billion, receives nearly 80,000 applications for support each year. Eighteen-thousand external scientists are recruited annually as reviewers of those applications to ensure the funds are invested in the highest quality research and training. As anyone in biomedical research can attest, applying for an NIH grant is increasingly dependent on professional grantsmanship. Awards are made to the most meritorious scientists and projects, following a rigorous review. This competition demands that substantially more and varied skills be applied to application preparation. While no organization could afford personal professional assistance on every application, a growing

number of research institutes are investing in grant development offices to support new investigators and large scale grant efforts in the over \$5 million range. This strategy is paying dividends at the Moores UCSD Cancer Center.

Large-scale projects were one immediate result of the National Cancer Act signed by President Nixon on December 23, 1971. The new law provided for unique authorities of the National Cancer Institute (NCI) director, and a \$100 million increase in the 1972 NCI budget, followed by similar proposed increases in the ensuing years; the creation of National Cancer Research and Demonstration Centers, originally called national cancer centers and now referred to as NCI-designated cancer centers (with an initial ceiling of \$5 million per center); large construction, training and contracted research programs to foster new approaches and resources in the war on cancer. It was not unusual to hire proposal writers and management consultants to coordinate the design and assembly of these formative grant proposals that would generate the centers of interdisciplinary cancer research and care envisioned in the legislation. Program project grant (PPG) applications, with their many scientific leaders, generally have been formulated by a senior investigator and assembled with the assistance of a central grants office, the principal investigator's (PI's) staff and perhaps his or her department's administrative office.

PPGs at the NCI and the NIH have an erratic history. As far back as the 1979-80 budget year, then Department of Health, Education and Welfare (HEW) Secretary Joseph Califano expressed concern over the future of federal support for biomedical research. He called for a stabilization plan for research funding agencies of HEW. The Plan was summarized in a 1985 Institute of Medicine background report entitled *Stabilizing the Funding of NIH and ADAMHA Research Project Grants*, authored by Richard L. Seggel. Among Califano's concerns was the growth of centers and large-scale projects. There was a two-fold dilemma: these grants were consuming an ever larger proportion of the budget and simultaneously driving down the success rate of other types of grant proposals. In 1993, Broder (then NCI director) and Cushing wrote about the support of research project grants (RPG) versus PPGs. This was at a time when NIH was seeking to maximize the number of awards it was making against its budget, ostensibly subordinating large-scale grants in favor of lower cost RPGs. While the number of PPGs awarded was fairly stable, the authors pointed out that PPGs have a high success rate, even if their funding didn't result in the requested or recommended levels. In the 1990s, PPG applicants had a 57% rate of success in obtaining funding. In contrast, competing R01 applicants were successful only 31% of the time. The success rate for PPGs from 1987 to 1992 ran about 20 points higher than the R01 rate. Thus, the PPG was an attractive opportunity for senior investigators. However, with the budget difficulties of the 1990s, new program-type grants were not heavily marketed by the NIH.

Fast forward to the 21st century. The NIH appears to have a renewed interest in the solicitation and funding of program-type grants, perhaps as a result of a doubling in budget, although more recently that growth has diminished considerably. The Congressional Research Service of the Library of Medicine submitted a report to Congress in 2006 which stated that the NIH appropriation from 2003 to 2006 has shifted from marked

growth to low or no increases. Congress doubled the budget in five years, from \$13.6 billion in FY 1998 to \$27.1 billion in FY 2003. Since then, growth has slowed to below the rate of inflation. The NIH issued more Requests for Applications (RFAs) and Program Announcements (PAs) in FY 2003 than in FY 1996 to highlight specific scientific areas. In FY 1996, NIH issued 99 RFAs; in FY 2003, 236 were issued. As a function of the total NIH appropriation, however, the number of RFAs peaked in FY 1999 at nearly 12 per \$1 billion. In comparison to the annual increase in the NIH budget, the number of RFAs issued fell during the doubling period, reaching 62 per \$1 billion of new money in FY 2003.

As an example, the NCI released RFA CA-00-001 “Interdisciplinary Research Teams for Molecular Target Assessment,” on November 10, 1999, with an application receipt date of March 15, 2000. Focusing on a fundamental topic in cancer research, the RFA stated that NCI sought teams to “discover, develop and validate the research tools that will make mechanism assessment in clinical trials and preclinical cancer models a reality.” The RFA used the U54, or Cooperative Agreement mechanism, an increasingly popular NCI tool for funding research, with NCI control somewhere between a grant and a contract that allowed the agency to more closely monitor the research without managing its performance. More recently, the NCI issued on June 30, 2009 Program Project grant (P01) policies in PAR-09-025. New guidelines covering letter of intent; requirement for NIH approval to submit an application at a financial threshold; electronic submission; multiple PIs, resource sharing plans and page limitations reinforce the need to provide more professional support to the grant application process.

The Approach

The Moores Cancer Center Grant Development Office (GDO) was created in 2004 in recognition of the need to acquire large science-type grants around which to build new programs and attract the highest performing scientists. A doctoral level scientist was chosen as GDO manager based on her previous biomedical research experience, oncology degree and interest in grant development. Administrative support staff were provided by the principal investigator’s team and the Cancer Center’s administration.

While this paper explores one approach to specialized grant development, it also acknowledges three alternatives.

The “do-it-yourself” approach is perhaps the most traditional. Many senior investigators have experience with large grant applications and can navigate their preparation with minimal support from their department’s administrative staff, including budgeting, biosketch collection/preparation, environment and resources sections.

A second approach is the use of a central facility accustomed to participating in large programs; the grants office is one example, biostatistics another. Biostatisticians serve the dual role of sharpening the research methodology while also helping to organize the data and format the proposal. The Grants Office may establish departmental or offsite bases.

Mason and Learned (2006) reported that emerging trends are to create satellite offices or new positions within the existing office to offer various support services required in the development process. Functions of these offices could include providing grant writing and professional expertise to attract federal and state funding, or providing expertise in technology transfer and intellectual property, primarily for faculty and staff in transferring basic research to the marketplace.

Grant development is also available through commercial firms that specialize in grant opportunities, sponsor identification, grant writing, and grantsmanship. As the need for professional grant development staff grows, so too does the field, with grant consultants making up another source of assistance.

The option of choice depends on the size of the organization, the number of large grants being submitted, the ongoing need for familiarity with the program setting, technical language of the RFA and application narrative and grant assembly team members, and, finally, the funds available to support grant development.

The Experience

Today, grant development cannot be the province of a single individual or even a single office. When grants of \$5 million to \$50 million are at stake, a concerted effort is required. But the use of the GDO is not determined by the grant budget alone. The GDO has been the “assembly plant” for cancer-related proposals generally fitting the following characteristics: NIH grants coded U or P; greater than 3 projects and greater than 3 cores; collaborators from more than 4 academic departments or schools of UCSD. Most are first time proposals in new technologies in response to funding opportunities.

Because the GDO is small, its deployment is limited to multidisciplinary, Cancer Center-wide proposals of high interest, competitiveness, priority and impact -- program and center grants that would further the Center’s scientific mission, direction, programmatic themes, and translation of research to patient-benefit.

Over the past four years the GDO participated in approximately 20 Cancer Center grant applications, pursuing support for centers of academic/industry partnerships in new therapeutics, nanotechnology, systems and integrative biology, training in drug development, molecular and cellular imaging; chemical biology consortium; cancer center/minority institution partnerships addressing cancer disparities; K12 in oncology clinical research training; physical science oncology center, and multiple shared instrumentation grants. Each of these initiatives was considered to be of both high priority and high impact. On average, the GDO is involved in 4-6 applications each year.

The process starts with the identification of a competitive opportunity by a Cancer Center senior leader, the prospective principal investigator, the GDO or another source. The opportunity is carefully vetted through various Cancer Center sources to determine

relevance to strategic goals, available resources and expertise, potential competition, principal investigator credentials, and institutional commitment. While not identical for every project, a general approach is taken once the decision is made to submit an application for a large scale grant.

The Project Team

First, an application project team is assembled. The team is led by the Principal Investigator (PI) and the Cancer Center administrator or GDO. The GDO is instrumental in coordinating the entire effort. The team is joined by budget and editorial specialists, and administrative assistants. The PI may bring in other co-investigators or work with them outside of the project team. As Porter (2007) notes, good grant writing requires teamwork from the outset. Because their ultimate success depends upon nearly unanimous approval from a sizeable group of reviewers, grant writers place high value on feedback at every phase of proposal writing. Thus, there are two teams working in tandem on the application, a program or faculty team and a support or administrative team. The PI works with his or her scientific colleagues on constructing content, and the Application Project Team works on assembling the entire application, focusing on the agency proposal criteria, budget, environment and resources, regulatory, and other administrative requirements. Each member of the team has a functional responsibility aligned with his or her skill and knowledge:

Principal Investigator: Senior scientist and director of the program responsible for scientific content and planning, program organization and scientific leadership, budget allocation, and identification of required resources.

Senior Administrator: Experienced in grant coordination, NIH policy and RFA interpretation, administrative leadership of grant assembly, budget oversight, institutional resources and general grant conditions and requirements.

Grant Development Officer: Familiar with RFA requirements and grant assembly coordination; serves as liaison with funding agency and institutional grant and regulatory offices; primary communicator to grant participants; creates iteration numbering system to preempt incorrect or duplicative editing of same manuscript version; oversees grant compilation, collation and shipment.

Grant Editor: Reviews manuscripts for flow, sentence structure, syntax and style;

Budget Specialist: Works with PI to construct budget according to agency and institutional rules; prepares worksheets, summary tables and internal forms; constructs and prepares recharge rates for core facilities; coordinates budgets of program components and any external collaborators.

Administrative Assistant: Knows NIH and institutional forms; requests information and follows up; manages meeting schedule; records minutes and action items of meetings; requests signatures on grant forms and letters of support.

Figure 1 below illustrates the grant process and flow from concept to completion.

Schedules

Once the decision was made to prepare a grant application, a Letter of Intent was submitted to the agency as required. The earlier the effort is launched, the more time is available to plan and prepare. A large scale effort requires a timeline of at least four months. Committees may then be created and a meeting schedule proposed. A critical component of the initial meetings is to draft a preparation timeline, including additional time to address last minute, unforeseen corrections/additions.

Meetings

A strict meeting schedule will help keep things on track. The meetings, either weekly or bi-weekly, require a quorum, an agenda and recording of action items. They also need a leader to keep the meetings on track, as there is usually more to cover than time allows. Shared leadership could be an effective alternative process as described by Easterly (2008). There may be two meetings. In one, the PI and a small group of colleagues join the administrative group; in the other, scientists and administrators meet separately, with integration of respective sections occurring outside of the meetings.

Manuscript Review

Of the many aspects of application assembly, the most problem prone is successive manuscript review. With multiple parties reading and editing the manuscripts it is important to develop a system to: 1) track changes (e.g., Microsoft Word Track Changes), and 2) avoid simultaneous review of each version by multiple parties. One individual needs to assume responsibility for controlling the flow of manuscripts. The GDO's approach was to update the version number each time it was distributed for review. Manuscript review should be a scheduled task, with each draft conforming to submission, review, and editing deadlines. Matching reviewer expertise to specific functions is important. Among the areas to be considered are text content and accuracy (particularly figures), adherence to preparation guidelines, cross-referencing among sections, budget, and grammar. Regardless of expertise, any reviewer may raise questions regarding the text.

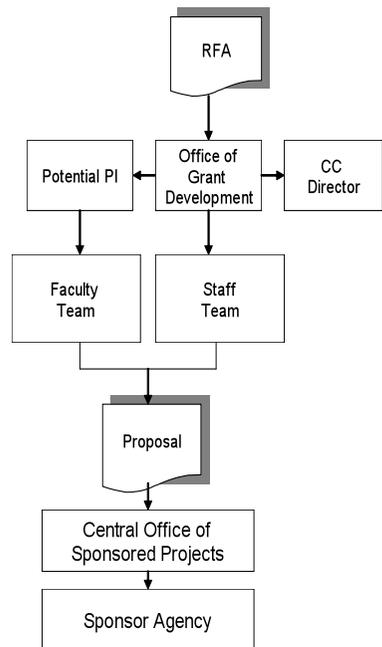


Figure 1. Large scale grant development process.

Financial Aspects

While the budget may not be a determining factor in an award, a well-documented presentation of the amount, description and integration of the overall budget will raise the reviewers' confidence that the grant will be well managed. Therefore, budget development is an integral part of the grant preparation process, and starting as early as possible will help ensure the described work can be carried out within the proposed funding. Budget cuts are an all too common part of the current review and award process. Cutting it too close during budget preparation could engender major, if not fatal, study design modifications at the time of a potential award. A reasonable and realistic budget is the best approach. The budget specialist should get institutional approval of the final budget as early as possible.

Measures of Success

Recognizing up front that not every application will be successful is prudent and realistic. However, unfunded applications may still prove useful. Thus, unfunded doesn't necessarily translate into unsuccessful. Indeed, every effort has a measure of success in the process alone. In our experience new grant development has been extraordinarily productive in establishing new collaborations; identifying new resources; creating new grant preparation procedures and systems, and building new centers of excellence that will seek other means of support. The GDO has witnessed consistent growth in knowledge, expertise and efficiency with every application submitted. The success rate of funded applications in which the GDO played a significant role is above 50%. Another measure of success is the innovation brought to the process by the MCC GDO. Table 1 presents a comparison of the conventional approach vs. the MCC GDO approach:

Table 1: Comparison of PI and GDO Functions

Conventional	GDO
Interpretation of RFA solely with PI	RFA interpretation shared between PI and GDO
PI manages the entire process	GDO manages the entire process
PI works according to his/her schedule	GDO prepares the grant assembly schedule
PI concerned with all aspect of proposal	PI concerned with scientific aspects only
PI prepares budget	GDO prepares budget
PI seeks help on administrative aspects	GDO prepares administrative aspects
PI calls group meetings	GDO calls meetings
PI invites selected staff to meetings	GDO invites all relevant parties to meetings
PI corresponds directly with collaborators	GDO corresponds with collaborators
PI seeks letters of support	GDO seeks letters of support

While these procedures are applied consistently in the large scale grant arena, many have made their way into smaller grant applications as well. However, given the size of the GDO, the services are more limited and selective for smaller grants.

Conclusion

This manuscript provides an historical overview of NCI program type grants and a contemporary approach to the preparation of large grant applications, with the following practical steps for future implementation:

- 1) Identify a grant development professional to coordinate application development and assembly;
- 2) Create a scorecard measuring your group against the competition, assuming a high probability of success before launch;
- 3) Compile a working group of administrative specialists with specific assignments;
- 4) Create a preparation schedule and adhere to it as closely as possible;
- 5) Build a manuscript review system that precludes simultaneously editing successive versions of the narrative;
- 6) Integrate the budget into the preparation process early and continuously;
- 7) Promote egalitarianism and openness in meetings to optimize expertise;
- 8) Never lose sight of the deadline date and monitor progress accordingly.

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