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PROFESSION

Dissecting, And Demystifying, An NIH Grant Application

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“I have been writing grant proposals the way I saw fit all my life, and I never had a problem until recently,” a Harvard Medical School emeritus professor told me some months ago, “but now my colleagues tell me I have to follow the instructions.”

I didn't appreciate the importance of certain details, either—until I began to review grant applications. Although much of the National Institutes of Health application packet is self-explanatory or is explained in the instructions, some insight from a former reviewer may ease the work of filling out your next application. I will use the NIH/PHS-398 form (ROI) as an example.

Although the initial pages in almost any grant application require seemingly straightforward administrative and financial information, you should give serious consideration to how you fill in the blanks.

When you decide on the title of the application, for example, keep in mind that it is one of the first things seen by the reviewer and by the referral officer in charge of assigning your proposal to the appropriate review board (study section). The title should be descriptive, specific, appropriate, and no more than 56 spaces long. When I entitled my first application “Control Mechanisms in Animal Cells,” my mentor pointed out that my chosen title might well send the proposal to the Institute of General Medical Sciences, where there was much competition and relatively little money. He suggested that by including the word “retina” (the tissue I was working with) in the title, I would increase the chance that the application would be directed to the National Eye Institute, which was newly formed and well endowed at the time.

The space marked “Dates of Entire Proposed Project Period” is another part of the application where some inexperienced applicants show their naivete by providing inappropriate responses. You should understand that the review process at NIH takes approximately nine months. (A table

showing application receipt dates with the corresponding earliest possible start dates is given in the instructions.)

One of the hardest things for some applicants to write is the description of the research plan (abstract). It is important not to exceed the space provided—and without using minuscule type. You will find it easy to satisfy the requirements and also save yourself some time if you simply treat the very specific instructions NIH provides as questions to be answered. My abstracts read: “The broad, long-term objective(s) of this proposal is (are).... The specific aims are... (1). . . (2)... (3).. .,” and so forth. Abstracts that begin with sentences such as, “For past 10 years I have been work-on.. .” are contrary to the NIH instructions (“Avoid summaries of past accomplishments,” and “Do not use the first person”), and indicate to the reviewer that the applicant does not follow directions.

Because your project is likely to evolve substantially as you develop it, you should write your abstract after you have written the rest of the proposal. Besides saving yourself the time and trouble of having to rewrite the abstract later, you will ensure that it parallels the content of the final version of your application. When reviewing applications in which the abstract did not reflect the contents of the proposal, I surmised that the applicants wrote the abstract prior to writing the rest of the proposal and neglected to change it after the project had changed appreciably. An abstract that does not accurately represent the proposal hints of a sloppy principal investigator. It also makes more work for the reviewers. Reviewers can use a well-written abstract as the proposal description for their reviewer’s report. If your abstract is not well-written, the reviewers will essentially have to write a new description for your proposal.

Another thing to consider is that the referral officers may use the abstract to assign your application to a particular study section. A good abstract will help ensure a good match with the most appropriate study section—one in which the members expertise is closely related to the work proposed in your application. In such cases, the reviewers are likely to know the field well, may know of your work, and may even know you personally. Members of study sections less close to your field are less likely to make cogent judgments about your work.

Perhaps more important, the abstract is one of the major things read by those members of the study section who are not the primary reviewers for that application but nonetheless get to vote and assign a priority score.

Having moved the abstract page to the rear of the application, you are now ready to take on the budget and its justification. You should spend a fair amount of time researching a realistic budget for the proposed project. If you try to give the granting agency “a bargain,” reviewers will probably end up thinking you’re naive and do not understand what it takes to carry out a project of this kind. On the other hand, it is important not to give the impression that you are an opportunist by over-budgeting to get extra

money. Foot-note budget items to correspond to the relevant explanation in the budget justification section. In the budget justification, justify just about everything. Many investigators neglect to justify personnel, often the largest cost. Specify what unique role each person will play in the execution of the research. Also, be sure to point out and explain any budgetary changes in later budget years.

Another piece of financial information you are expected to give is a listing of your “Other Support.” When filling out this page, be totally honest. A notice in the Feb. 3, 1989 (vol. 18, no. 3), issue of the *NIH Guide for Grants and Contracts* warns applicants that “serious consequences” could result if they do not provide complete and accurate information.

The information you give in the “Resources and Environment” section must be nowhere at odds with any budget request. For example, if you request a microscope and then under “Resources and Environment” say your department has three such microscopes, only a very strong justification will keep your request from deletion from the budget. Also, often neglected in this section is some description of the scientific atmosphere at your institution. For example, it is wise to mention factors that enhance the working environment, such as colleagues with whom you can intelligently discuss your project.

The research plan (in Section 2 in the NIH ROI application), which has four major subsections, is the most important section of any grant application. Do not exceed the specified page limitations.

In the subsection of the research plan entitled “Specific Aims,” you are to describe, in about one page, what you intend to do and what your research is intended to accomplish, preferably in the form of hypotheses to be tested or a set of clear, specific questions. “To test the hypothesis that reaction X is the rate-limiting step in the mechanism of is a good specific aim. “To study the effect of substance X on the system Y” is not a good specific aim. You should understand—and define for the reviewer—the difference between your broad, long-term objectives and your specific aims.

Respond To Objectives

The “Background and Significance” subsection is where you relate, in two or three pages, what has already been done in the field and why the work is important. You must respond to four specific objectives:

- (1) sketch the background for the proposal, making it clear which work was done by others and which was done by you, the applicant;
- (2)critically evaluate the existing knowledge;
- (3) specify the gaps the project is intended to fill; and

(4) explain the importance of the research by relating the specific aims to the broad, long-term objectives. This section of the proposal (especially the background) should be amply referenced. (The author/year citation method is much more meaningful to reviewers than numbered references, because it saves them the trouble of having to flip back and forth to the bibliography. However, this method of citation does take more space and, if there are numerous multiple citations, can make reading the text more difficult.)

In the subsection entitled “Preliminary Studies” (for new applications) or “Progress Report” (for renewal applications), you are to delineate (in six to eight pages for the narrative portion) what you have already accomplished on your project. Although “Preliminary Studies” is said to be optional for new applicants, I suggest you consider it mandatory. This is your opportunity to discuss pilot experiments that you have done and to provide other information that helps to establish your experience and competence to pursue the proposed project.

In a renewal application, the "Progress REport" is your opportunity to summarize the specific aims of the preceding application and to give a succinct account of your progress toward achieving them. Do not just list your findings; rather, summarize the importance of what you have found, and discuss any changes in the original specific aims. This subsection also requires a listing of your pertinent publications. Unless you get special permission, do not list papers that have been submitted but not accepted, or manuscripts that are simply in preparation.

The subsection entitled “Experimental Design and Methods” is where you describe (in about eight to 11 pages) how you will fulfill the specific aims and how you will do the work. Distinguish between the overall experimental design and the specific methods. It is best to outline this section for each specific aim separately. First, repeat the specific aim, so the reviewer does not have to flip back to an earlier page. Then, outline the experimental design, so the reviewer clearly understands the overall approach. Next, describe specific procedures within the context of this overall design. If identical procedures apply to more than one specific aim, don't repeat them; describe them once and then refer the reader back to the relevant section.

Important items often inadequately discussed in this section of the proposal—or omitted altogether—are

- (1) control experiments;
- (2) how the data will be collected, analyzed, and interpreted;
- (3) potential limitations and difficulties of the proposed procedures;
- (4) alternative approaches to achieve the specific aims; and

(5) procedures, situations, or materials that may be hazardous to personnel and the necessary precautions to be taken. A tentative sequence or timetable also is required in this section to tell reviewers when certain aspects of the work will be started and finished in the course of the complete project period, and to convince them that you have carefully thought the project through.

Also part of the research plan is "Literature Cited," in which you provide bibliography of no more than four pages. Select the most important and pertinent references in the field and demonstrate to your reviewers that you have a current, unbiased, and in-depth knowledge of the literature.

Providing article titles in the bibliography is optional, but very helpful to reviewers. On the other hand, titles take up precious space. List your references in a consistent, conventional format, and be sure that every citation in the text is listed in the bibliography (and vice versa). If your bibliography contains obscure references that were troublesome to obtain, include two photocopies of the article—or at least the summary—for the primary reviewers.

The Appendix is for supplementary materials, relevant to the proposal, that are either oversized or difficult to reproduce, as well as for reprints of publications either in print or accepted for publication (maximum of 10). This is also the place to include materials that may save the primary reviewers a trip to the library. Each Appendix item should be referred to in the text of the application, and each Appendix item should be numbered as referred to in the text. You will garner disfavor and may have your application returned without review—if you use the Appendix to circumvent the page limitations in the research plan.

After you have completed the application, it is wise to go back and read it over, bearing in mind NIH's warning that "an application will be considered incomplete and returned [to the principal investigator] if it is illegible, if it fails to follow the instructions, or if the material presented is insufficient to permit adequate review."

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