ABCT
ASSOCIATION FOR BEHAVIORAL
AND COGNITIVE THERAPIES

From *the Behavior Therapist*, Vol. 26, #3, pp. 258-261, March 2003

Hints for Writing a NIMH Grant Proposal

Dianne L. Chambless, *University of North Carolina at Chapel Hill*

Getting funding to do your research is desirable for several reasons: Much research is impossible to do without significant external funding; you may provide financial support for graduate students and for yourself; and your institution may consider external funding to be important in evaluations for promotion, tenure, and merit pay raises. Given all these benefits, why isn't everyone doing it? Writing an application is effortful, and the payoff is uncertain. Depending on the funding year, 15% to 20% of applications to the National Institute of Mental Health (NIMH) programs with which I'm familiar may be funded. Also, the process itself may seem daunting, perhaps accessible only to those gifted in what's known as grantsmanship, and passed down from successful mentors to their acolytes.

The purpose of this article is to give you some of that insider information and thus perhaps the necessary encouragement to write applications and obtain funding for your work. Keep three caveats in mind: First, my experience is limited to the review process for NIMH study sections (now called initial review groups or IRGs) for psychotherapy and other intervention research. Second, much of what I will say is based on my perception and, as such, may well be wrong. Third, with each new head of the NIH, review processes are changed, and IRGs are constituted and reconstituted. Some of what I have to say here may only pertain until the next, seemingly inevitable, reorganization. Kendall and Coles (see p. 254) have described a variety of mechanisms for funding. I will focus on the most common, the R01. The R01 may be a single application from one institution or a coordinated group of applications from investigators at two or more institutions applying to conduct multisite research (for the latter, see http://grants.nih.gov/grants/guide/pa-files/PAR-98-107.html). The separate R10 mechanism for multisite grants no longer exists, but, using the multisite R01, the principal investigator (PI) at each institution is credited with being a PI. This can be important for career advancement in that institutions give more credit to the person serving as PI than to those in co-PI roles.

Review Criteria

Reviewers follow broad formal guidelines provided by NIMH, and, over time, IRGs also develop informal criteria by which they interpret the specific applications of these guidelines. The formal criteria are significance, the approach, innovation, the investigator, the environment, and the adequacy of the plans for inclusion of children, women, and ethnic minorities, and for monitoring the safety of research participants and the integrity of the data.

Significance

Applications are judged on the basis of the scientific significance of the work and the public health significance. A relatively recent change at NIMH is that public participants are now included on IRGs. This step was taken, in large part, to have mental health consumers' (e.g., clinicians, state mental health administrators, patients, or their families) voices heard in evaluations of significance. One powerful NIMH administrator commented to the committee that he was tired of elegant applications that proposed new studies of well-studied phenomena; rather, he wanted research on understudied areas or on applications of research to real-world settings (i.e., what is called *effectiveness research*; see NIMH's document "Bridging Science and Service," available at http://www.nimh.nih.gov/publist/nih4353.cfm). It seems to me that IRG members differ in how much they adhere to this instruction and that your chances of being funded for theoretically meaningful work without strong immediate public health significance will vary unpredictably according to the reviewers to whom you are assigned. Nonetheless, one of your reviewers will be a public participant who will be instructed to evaluate the grant by that criterion. It behooves you to make as strong and clear a case as you can for the significance of your proposed research. The disease model of mental health problems predominates, and it can be difficult to get funding from NIMH if you deviate from that. If you're interested in positive psychology, you would do well to apply to private foundations instead.

Note that the IRG does not have the last word on your chances of funding. Technically, the IRG simply provides advice to the overall NIMH council and to program officers (the people who hand out the money and supervise your administration of the work). Program officers are sensitive to the priorities of the institute and are free to go out of order of the IRG's priority scores to fund proposals they think are significant to the mission of the NIMH. In practice, they are unlikely to devi-

ate wildly from the IRG's recommendations, or IRGs would revolt. Nonetheless, it is easier to get funding in an area the program office thinks is highly significant, for example, research on children or severe mental illness. When NIMH particularly wants to stimulate research in a given area, officials may issue a program announcement (PA), encouraging researchers to write particular types of applications. The researcher indicates on the front page of the grant application whether the application is in response to a program announcement, in which case the reviewers will look at the criteria specified by the announcement before conducting their review. It is worthwhile to check for program announcements that might pertain to your research (go to http://grants2.nih.gov/grants/guide/index.html).

Approach

This is the heart of the proposal and of its review. No matter how important your research question is, if you don't do well here, you won't get funded. Steve Hollon and I have elsewhere described the elements we think are crucial for good psychotherapy research (Chambless & Hollon, 1998). In part, we gleaned these ideas from our experience on IRGs. These points are too lengthy to repeat in detail here, but I will include them briefly in my description of the issues you should consider.

Here are questions to ask yourself: Are the conceptual and empirical bases of your proposed research clear, and do they make a compelling argument for your research as the next logical step? Does your proposed methodology follow logically from your hypotheses and test them adequately? Do you have pilot work that indicates you can do what you say you will do and that it is reasonable to think it will pay off? The reviewers will be looking to see that you have clear and reasonable inclusion and exclusion criteria for your sample, that you use reliable and valid measures (when possible, include measures that are the gold standards in the field), that you have manuals for your intervention protocols as well as measures of treatment integrity and, perhaps, ratings for therapist competence. Reviewers will examine your design. Have you ruled out important threats to internal and construct validity and made it clear how you did this? It would be reasonable to think that, with the focus on effectiveness research, IRGs would consider quasi-experimental designs to be appropriate for funding. I have yet to see this happen, although advances in quasi-experimentation permit a high level of internal validity in such a design (see Shadish, Cook, & Campbell, 2002). So far, the IRG on which I serve seems only to be comfortable with the standard randomized controlled trial, even in effectiveness research and certainly in efficacy research.

An important change in recent years is the increased emphasis on statistical issues. In my IRG, each grant will be assigned a statistician as a reviewer. That person may know little about the substance of your area and will be primarily examining the data analysis and perhaps other areas of methodology. The statisticians look for a detailed, sophisticated approach to data analysis and are more favorable toward applications that include a statistician among the key personnel. Make clear your statistician's expertise in the types of analysis you plan to use if it is not apparent from his or her publications. Include power analyses and describe the basis for these analyses, and make clear links between the statistical analyses and the research hypotheses.

Finally, you need a good implementation plan. Include a time line for the proposal. For example, how long will you spend training raters and therapists before you begin to see the first real participants? How will you decide the therapists are competent at the proposed treatment? How will you determine interrater reliability of interview data? How will you recruit subjects? Who will take responsibility for what in the project? Have your manuals and rating scales been pilot tested? Where multisite applications are involved, a special section on coordination between sites is required. Spell out how decisions will be made, which site will be responsible for what tasks, how cross-site consistency will be ensured, and so on.

Innovation

Applications deemed to be innovative get better priority scores, other things being equal. There are a number of different ways you can prepare an innovative application. One important approach is to conduct research with an understudied population, such as children, the aged, those with severe mental illness, or those living in rural areas. In short, go where others aren't. If your research could be carried out in the arena of alcohol or substance abuse or health problems, you have a real advantage. Funding is easier to obtain at the National Institute on Drug Abuse (NIDA) and the National Institute on Alcohol Abuse and Alcoholism (NIAAA) than at NIMH and at the various institutes for physical health problems. A second type of innovation is the study of effectiveness, the benefits of treatment in real-world settings. If you've been working with a treatment shown to be efficacious in tightly controlled settings, consider testing this therapy in primary care settings or community agencies.

NIMH would also like to see research on cost-effectiveness included in effectiveness studies. Incorporate such analyses only if you have the relevant expertise or can find a collaborator who does. The IRG includes health economists who will look at your proposal almost entirely through those eyes. At this point, it seems that no cost-effective analyses would be better than ones that are not state-of-the-art. Of course, new treatments for problems that have proved refractory to available therapies or treatments for problems that have not often been the subject of controlled treatment research constitute another kind of innovation, as do new methodological approaches, such as applications of emerging technologies.

Investigator

Funding an application requires faith in the research team's ability to complete the research in a high-quality fashion. The reviewers use the quality of the proposal to do this, but they also consider the investigators themselves. Here the biosketch is useful for demonstrating prior research in the area of

your proposal as well as your general productivity, and the reviewers may be influenced by what they know of your overall scientific reputation. In the body of the application, you can describe your training and experience for the proposed tasks and demonstrate with pilot work that you can carry out the proposed research. Does this work to the disadvantage of less experienced investigators? It certainly may.

There are several ways to get around this. First, NIMH wishes to encourage new investigators, and you are invited to indicate on the application face page if you are such a person (e.g., someone relatively new to the field who has not previously had an R01). In such cases, the IRG is asked to consider the potential of the investigator more than the past track record and to expect less extensive preliminary research. Second, you can include more experienced co-investigators or consultants to shore up the IRG's confidence, as well as to help you conduct an excellent project. Third, start small. Build up your track record by completing a smaller project that heads you in the direction you want to go but without such high stakes. Kendall and Coles (see p. 254) describe the R03 small grant mechanism, which is, in part, intended for new investigators.

Environment

You can be a wonderful investigator with a great idea, but if the IRG doubts that you can carry out the research in the proposed setting, you're sunk. When you describe the environment, indicate all the resources (programs, space, equipment, and people) available to you at your institution and at any other sites where you plan to conduct your research. In particular, document that the patient flow is adequate to fill the cells of your trial. If you will interface with other agencies, for example, for recruitment, then include supporting letters in which the responsible individuals at those agencies indicate their agreement to participate.

Human Subjects

The recent deaths of participants in medical research trials have increased the intensity of NIH's focus on safety of human subjects in all treatment research. Reviewers are expected to downgrade your priority score if they have significant questions about the safety of your procedures and whether you have sufficiently protected the welfare of your participants. The human subjects section and the safety-monitoring plan will come in for close scrutiny. The public participants are asked to comment on these aspects of your application in their reviews, and they will also weigh in on the burden to participants of taking part in your study. More than ever, you will be expected to describe when you would decide to remove participants from a trial for their welfare, how you provide emergency coverage, and how you will handle adverse events. All personnel who have contact with human participants or their identifiable data are required to have a certificate of training in ethics. Large-scale studies and multisite studies require that the researcher establish a formal board, including people who are not project personnel, to monitor the safety of human subjects.

Inclusion of Women, Minorities, and Children

You are now required to include sections describing your plans for inclusion of women, minorities, and children (defined as subjects less than 21 years old) in your research. Do not make light of these sections or omit them. This is NIH's way of trying to get researchers to increase the amount of available data on these subgroups. Few psychotherapy researchers have trouble including women in their studies; this is more of an issue for health or medical researchers, who have often omitted women from their samples.

If you study geriatric problems, your rationale for omission of children is clear. Otherwise, you need to include them or have a good reason why you're not going to do so (for example, if the intervention you plan to use is not developmentally appropriate for children).

Indicating that you will include minorities insofar as they apply to your project and that you hope to match the demographics of your geographic area no longer suffices. Rather, you need to describe the ethnic makeup of your facility's clientele and, if this provides insufficient minority representation (as it often will), you need to develop a specific plan for recruitment of minorities.

Data and Safety Monitoring Plan

The importance and some of the features of the safety-monitoring plan have already been described in the human subjects section. Often overlooked is the requirement for a data-monitoring plan. For large-scale and multisite grants, this comes under the review of the Data and Safety Monitoring Board, which Steve Hollon (see p. 261) will describe. Otherwise, the PI and perhaps the project statistician may serve this role. You should provide your plan to ensure accuracy of data entry, backup routines, and checks to further verify the validity of the data. For multisite projects, indicate how data will be transmitted from one site to another.

Overall Strategies

Write a Good Proposal

Allow yourself time to prepare your proposal carefully and to have one or more colleagues read it over, preferably one colleague who is in your specific field and one who is not. The reviewers will judge you by your written proposal, especially if you are a new investigator about whom they know little else. They are likely to conclude that an inconsistent, sloppy, or poorly written proposal means that you are an inconsistent, sloppy, poor investigator.

Discuss and Defend All Important Decisions

There is often more than one way of doing something, and someone will disagree with whatever you do in these cases. For example, you may choose to control for therapist characteristics by crossing therapists with condition (i.e., having each therapist provide each treatment that is being compared with another). Some people will think this is a fine idea. Others will worry that your therapists will not be able to keep the treatment conditions distinct, or that they will have an allegiance to one treatment over another. What to do? Demonstrate that you understand the potential problems and have thought about why you've decided to do it the way you have. Back yourself up with data, if possible. For example, if you choose to cross therapists with condition, then show that in pilot work your integrity measures indicated that therapists maintained the boundaries between treatments (presuming this is the case).

Obtain Feasibility Data

Before you start a large-scale project, demonstrate that the procedures you are planning to use can be carried out. For example, say you want to train therapists in the community to conduct a particular kind of treatment. You need to show that you can get these therapists involved in the project and that your training plan and materials are adequate to the job. Again, this means you'll likely need a pilot study. It is highly unlikely that you will be funded to carry out a full-scale intervention study unless you have conducted such pilot research, resulting in the development of fully elaborated treatment manuals, integrity measures, and competence ratings, and providing estimates of effect size for your power analyses. This pilot research may involve 2 to 3 years of work. A special funding mechanism, the R21, exists to enable you to carry out such research before you submit an application for an R01 (see program announcement at http://grants2.nih.gov/grants/guide/pa-files/PA-99-134.html).

Persist

Be prepared to be rejected and to bounce back. Resilience will serve you well in obtaining a grant, just as it does in getting published. You will receive the comments of at least several reviewers on your application, and you may get a summary of the discussion of the IRG meeting as well. (To save IRG time, applications that the assigned reviewers find to be in the lower 50% of priority scores are not discussed at the meeting. Thus, you will not receive a summary if your application falls in this category, called unscored.) Consider the critiques carefully and decide whether you think your project is basically a sound one, or can become so with additional work. If the message is at all encouraging, plan to revise and resubmit the application, perhaps after doing additional pilot work to address the IRG's concerns. Don't assume that, if your application was unscored, the IRG is saying it is without merit. That is often not the case; you need to read the critiques (called pink sheets because in the old days they were printed on pink paper). Program officers often attend the IRG meetings as observers and can provide you with additional feedback about the reaction of the group to your work, thus helping you decide whether and how to resubmit. Please do not contact members of the IRG. We are not allowed to talk with you about the content of the meeting or about our thoughts concerning your application. For a resubmission, you will get additional introductory pages to specify your response to the IRG's critique, in particular, what changes you've made. If you believe the IRG was flat-out wrong about some point, then think of a respectful way to explain why your original plan was the best approach. Make sure you go through the application and carry any changes throughout. Don't waste a resubmission with hasty work. NIMH will only consider two resubmissions now of a given project: Three strikes and you're out.

Summary

The process may seem daunting, and indeed it is hard work. However, writing an application almost always sharpens your thinking about your work, and you may shape the introduction to a journal article or the bulk of a book chapter from your background and significance section. You will often get a very careful reading of your ideas with valuable feedback you couldn't buy from experts in your field. The reinforcement schedule is intermittent, but the rewards are potent when they come.

References

Chambless, D. L., & Hollon, S. (1998). Defining empirically supported therapies. *Journal of Consulting and Clinical Psychology, 66*, 7-18.

Shadish, W. R., Cook, T. D., & Campbell, D. T. (2002). *Experimental and quasi-experimental design for generalized causal inference*. New York: Houghton Mifflin. ✍