Tips for Writing Successful Grants to NIH (and Others)

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The following "tips guide" addresses the "secrets" of writing successful grants. It focuses on applications by SJSU faculty and staff to the National Institute of Health (NIH) in particular, but can be applied to all governmental and private grant-supporting institutions. The information provided here is not meant to minimize the use of official NIH guides. Much of what follows is derived from the personal experience of grant writers, from conversations with and presentations to NIH program and grant officers, and from helpful websites, such as the wonderful website put forward by the National Institute on Allergies and Other Infectious Diseases (NIAID). While some of the advice below also applies to contract applications, this guide is geared to the grant world.

This guide is divided into several sections. It begins with a discussion of a general overall application strategy, and then turns to tips specifically targeting the most recent official 9-point research outline (Form 424) on significance, approach, innovation, and timetable.

I. Being Strategic

Getting Started

- Select a research area that "fits" your knowledge realm, expertise, and career path.
- Find a program announcement (FOA) or an organized section of an NIH Institute that is the best match for your research area and question.
- Prepare a two-page summary of your research concept.
- Pass the "2-pager concept" around to your colleagues for feedback and suggestions.
- THEN call or write the program officer assigned to the program announcement or the branch chief of the appropriate section. Ask the program officer/branch chief if the institute would be interested in this submission (sending the 2 pager) without being afraid to "push" for suggestions for the best research strategy. Ask that program officer for help in locating current or past principal investigators who have been funded in your research area (*do this even when you are responding to an RFA*).

Which Mechanism?

The question of whether to submit a R01, R21, or R03 is always asked.

R01

The R01 is the research engine. Usually the time span for grants is 3-5 years. The R01's funding level limit is not specified. You must get written permission to ask for $500,000 or more per year. In general, don't ask. To ask means developing almost a full proposal and months of delay with frequent rejection. If you see the budget going over $500K for any year of the proposal, figure out a way to "flatten the budget" (*i.e.*, spread it out to keep each year under $500K). In fact, it is a good idea to flatten the budget in general. Budget requests under $250K need to be modularized (in $25,000 increments: $75,000, 100,000, 125, 000 etc.).

R21

Most R21s focus on the developing and testing of a new concept, instrument, or secondary data analysis. If you have a qualitative study in mind, you might want to look at this R21 mechanism because its positive review is less dependent on experimental/control group trials.

R03

Use the R03 if you are following through on a dissertation and/or have a tight pilot study in mind, that is, one with a single hypothesis and the need for only 18-24 months for the study.

R36

The new R36 is ideal for testing interventions before going the whole route of a clinical trial.

While the R21 is considered for conceptual oriented grants (under $225K over two years) it may be wiser for new investigators (first application, less than 10 years after receiving Ph.D.) to apply for an R01. Your odds as a new investigator have been proven to be better pursuing the R01 over the R21. Other mechanisms, such as the R15, R24, PO1, K's and F's, concern training, infrastructure, and research centers and are not discussed in this research grant-oriented guide.

Significance, Impact, Feasibility, Sustainability

The significance, impact, feasibility, and sustainability (where relevant) will be important points to address in your application. Put yourself in the reviewers' shoes. How will they evaluate your proposal on these terms? Ask your program officer (or call an NIH grant officer if listed on the FOA) for information about which study section is likely to review the group. You can also find out yourself by looking up the study sections on the NIH CSR Study Section Roster Index, and make a best guess. Identify people who might serve as your reviewers. Then look at what they have published, and see if you can spot a bias/point of view that agrees or may conflict with your research question, direction, or theoretical base. If so, be sure to address it and, if possible, cite their work in your proposal. *Be aware that you are not allowed to request reviewers in your cover letter. But it is a very good idea to include a cover letter requesting a study section when you submit your application.*

Working with the SJSU Research Foundation

If you decide to proceed with your application, IMMEDIATELY inform your SJSU Research Foundation pre-award grant officer and cc your chair/dean. Inform him/her in an email: (1) the tentative title of the research, (2) a tentative abstract (send the two pager!), (3) if you are responding to a specific FOA (PA/RFA), (4) the funding agency/institute you will be approaching, (5) the grant deadline, and (6) the budget scope and, where possible, the budget particulars, such as the people who are to be funded, the funding level, the role/capacity of each participant, and the space and equipment needed. It is extremely important to tell the Research Foundation early on if you intend to use or affiliate with outside (external to SJSU) consultants, universities, or agencies. Yes, it feels like a bother especially when you have to guestimate so much on the particulars at the very start, but experience has shown that addressing these questions from the beginning will speed up the clarity of thinking and writing—not to mention allowing time for the considerable administrative work that will be needed to back up your grant! The signatures (*i.e*, sign-offs), memos of understanding, and subcontracts all take time! And remember, it is the SJSU Research Foundation that submits the electronic grant, not you! And indeed, that's the gift; your role is to send the SJSURF sponsored programs manager the narrative according to NIH guidelines, and the SJSURF personnel work with you on the rest.

Compliance

Closely after that, you should become familiar with the Human Subjects Institutional Review Board or the Institutional Animal Care and Use Committee procedures for filing an application if your work will involve either human subjects or animals. A data safety

monitor plan must also be in place, should you be submitting a substantial clinical trial plan. The NIH Institutes have come to accept a letter from your IRB office noting SJSU IRB's awareness of the application and an assurance that, should the grant be funded, no aspect of the grant that entails involvement of human subjects shall proceed until the work has been reviewed and approved by the IRB. A similar procedure is to be followed with regard to animal protections with the Institutional Animal Care and Use Committee. Fortunately, SJSU has established procedures (see links on the Office of research website for **IRB** and **IACUC**).

The Writing and Research Design

Remember, reviewers are reading a large stack of applications. So keep your writing simple, and strive to have a unique label or term for your project as a way for the reviewer to ferret out your application from all the others that he/she will present to the larger scoring study section. Thus, "connect the dots." Don't assume reviewers will make the connection between the importance of the problem and how it will move the field forward. The more diverse the review group, the more you'll need to explain the significance of your research. Paraphrasing from the NIAID website noted earlier:

Drive home the big picture. Your assigned reviewers may read your application piecemeal. So in every section, remind them of your goals and research questions.

Streamline. Don't put anything in your Research Strategy you don't plan to do! Keep it lean. The more you put in, the greater your chances of making a mistake or giving reviewers something to fault.

Be very careful with technical material. Some reviewers may be better informed about your field than you.

Use graphics. Include graphics and timetables to illustrate the flow for your experiments and personnel. Chart your experiments with decision trees showing alternative pathways should you get negative results. **Many reviewers pay more attention to the charts, timetables, and graphics then to the written narrative!**

Omit confidential information unless you are submitting a patent application.

Yes, **it pays to be pedantic** (actually be careful that the reader follows your roadmap), expecting neither a careful reading nor any filling in of steps in a logical argument. Thus, spell out the hypotheses, expected results, conclusions if those results are acquired, and conclusions should unexpected results occur. Organizing the entire proposal around this kind of presentation is an effective means of ensuring clarity and completeness. (NSF applications in this format have been successful).

And finally, **do not include an introduction for** New NIH Application, as was required for the application previous to 2010. However, I still recommend opening lines that help the reviewer home in on the "story" and direction of the principal investigator's (PIs) proposal. So when the reviewer begins reading the state of the problem/science/ literature review, he/she "gets early on" why one needs to know this information (the significance or need for the research) and that it will lead to the specific research hypotheses, data, and conclusions.

The reviewers are looking to see whether you have designed your research to answer the question posed by your hypothesis. Is your hypothesis sound and important? Will the research make a high impact on its field? Are your specific aims logical and feasible? Do you understand potential problems that may detract from your research findings? Will unexpected results have significance and lead to alternative hypotheses? Will your qualitative or quantitative experiments result in usable data? And if you get data that require advanced statistical analysis, are you or your team able to conduct the necessary statistical procedures and derive meaningful explanations? Be especially aware that preliminary studies can help demonstrate your strength in this area. To a great extent, the lack of preliminary data is a death knell in many areas of study.

II. Points Specific to the 424 Form for NIH

The 1-9 variable score is universally based on:

- **Significance and feasibility**
- **Approach**
- **Innovation**
- **Timetable, resources**

Significance and Feasibility

Significance and feasibility means impact. Can the topic pass the "so what?" test? If reviewers do not believe the question is important, it won't matter that your approach is feasible.

Approach

The approach in your research plan describes what you are proposing to do, why the research is important, and how you will carry it out. Design your research to answer the questions posed by your hypothesis. Throughout the research plan, give enough detail to convince reviewers that your hypotheses are sound and important and that your specific aims are logical and feasible. Limit your hypotheses to one or two and accordingly limit

your aims. Choose specific aims peer reviewers can easily assess. Each one should be an achievable end point rather than a best effort. Follow the designated format of abstract/summary, significance, innovation, and approach.

Think of various, interesting pathways you could pursue depending on your results. For example, give details for initial experiments, then show branching depending on the outcome of the research: if this works you will do X; if it doesn't you will do Y. Although you need to provide enough detail to show reviewers that you understand the scope of the undertaking, still spend more time on the research strategy than on the details of methodology. This is especially true since the number of pages was limited for proposals in January 2010.

Note any potential problems in the research strategy while convincing the reviewers that your study will result in usable data that you and/or your team has the statistical and methodological savvy to analyze and interpret (here is where preliminary studies can help demonstrate either one). Reference any published methods. If you are an experienced investigator, cite relevant work so reviewers will know of your expertise. For new investigators, cite experience in using the experimental methodology. If you lack key expertise, make sure to refer to the others on your team who do have the relevant expertise and tailor the bio-sketch accordingly (and note new NIH bio-sketch rules!). Finally, insist that you and your team are the ideal candidates and have excellent institutional support to perform this research. The Office of research and the SJSU Research Foundation can help you tailor the facilities, resources, and equipment descriptions and prepare biographical sketches in the NIH/federal format.

Innovation

It can be difficult to finesse innovation. Generally, show how the work is new and unique and how it will add significantly to the field. Stick to explaining how your project will refine, improve, or propose a new application of an existing concept, method or instrumentation, or clinical intervention, or how it could shift a current paradigm.

If you believe your application is highly innovative, you will need to build a strong case for your ability to challenge the existing paradigm and your reason for doing so. In this case, it would be most advisable to obtain outside senior collaboration to substantiate your claim.

Timetable

Reviewers appreciate having a timeline that shows how and when you will accomplish your objectives, including any overlap of experiments and alternative paths.

Include flowcharts and decision trees to show paths of experiments and how they progress, including alternatives, that is, what you will do if you get "negative" results. If you used graphics to plan the project, put them in the application. (Often, the timetable may be linked to the budget discussion).

Consultants

Consider relying on consultants to fill in needed expertise. State how collaborators or consultants will fit into the project. Then list them as key personnel and provide bio-sketches.

Checklist Taken from NIAID Website

Do your assessment by answering the following questions:

- Do your specific aims address the hypothesis?
- Is the order of the specific aims and experiments appropriate?
- Did you give details but omit anything not essential?
- Did you justify a highly innovative application?
- Did you justify an application that aims to make an incremental advance over existing knowledge?
- Is the approach feasible?
- Did you defend the choice of study design? Did you state expected results and how they would support continuing the project?
- Did you convince reviewers you chose the right methods?
- Did you describe how you will gain access to reagents or equipment? If collaborators will provide them, did you include letters of support describing their agreements with you, including their role on the project?
- Are the procedures within your competence?
- Did you propose a realistic level of work for the allotted time? Did you estimate how much you expect to accomplish each year and state any delays you can anticipate?
- Did you describe limitations to your approach and how they may affect results and data?
- Did you call attention to potential difficulties and propose alternatives?
- Did you show that you know how to handle results?
- If using animals or human subjects, did you include all the necessary details?
- Did you define the criteria for evaluating success or failure of each experiment?
- Will the experiments yield statistically significant results?
- Did you include a statistical analysis to impress reviewers?

- Did you describe your statistical methods for analyzing data you plan to collect?
- Did you provide enough information -- methods of data analysis, power calculations, and justification for proposed sample size -- that peer reviewers can evaluate your approach?
- Did you hire a statistician early on to advise you on sample sizes and the amount of data you'll need to collect?
- Did you include well-designed tables and figures that have accurate and informative titles to meet reviewers' expectations for supporting data?
- Did you label the axes and include legends so reviewers won't find discrepancies between your data and text?
- Did you check and double check your data to avoid glitches?
- Did you show you are aware of the limits to -- and value of -- the results you can expect based on current knowledge?
- Did you state the conditions under which your data would support or contradict your hypothesis and your limits for interpreting results?
- If using hazardous materials, did you note the special facilities you can access for protecting the environment and staff?
- Did you describe the precautions you will take in handling the materials?
- Did you describe the training people involved have had in safe practices?