Tips and strategies for NIH grant writing

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Overview

- My most important advice
- Key resources
- Mechanisms
- Format
- Review criteria
- Tricks of the trade
A bit about my NIH funding experiences

- Funded on NIDA minority (now diversity) supplement to an R01 as a pre-doc
- PI on two NIDA-funded R01s and one R21
- Co-I on several NIH R01s (NIDA, NIMH, and NIA) and an R24 (NIMHD)
- Recipient of NIH Loan Repayment Program
- NIH grant reviewer
- I’ve had my fair share of grants rejected

• NB: I only work with humans
Most important pieces of advice

• Understand the funding mechanisms
  – Read the Funding Opportunity Announcement (FOAs) closely
  – Call the project officer

• Follow directions
  – Follow the format directions
  – Looks for special instructions in the FOAs

• Strategize
  – Incorporate the review criteria into your DNA
  – Look at the study section composition
  – Do an NIH RePORTER search to see who is working and NIH-funded in your area

• Talk to the research office as soon as you know you want to submit a grant
KEY RESOURCES
NIH Funding Opportunities and Notices (The NIH Guide TOC)

• Weekly email with new FOAs
  – To Subscribe to the NIH Guide LISTSERV, send an e-mail to listserv@list.nih.gov with the following text in the message body (not the "Subject" line):
    • subscribe NIHTOC-L your name
      – (Example: subscribe NIHTOC-L Bill Jones)
    • Your e-mail address will be automatically obtained from the e-mail message and add you to the LISTSERV.
NIH RePORTER

• Research Portfolio Online Reporting Tools
• Provides access to reports, data, and analyses of NIH research activities, including information on NIH expenditures and the results of NIH supported research
  – You can get some details on funded projects
• http://projectreporter.nih.gov/reporter.cfm
Project Information
5R01HD065137-05

Abstract Text:

DESCRIPTION (provided by applicant): A decade after the end of apartheid, the well-being of South African children is still in a precarious state. Nearly 70% of the nation’s Black African children live in households with incomes less than $2000 per year. The HIV/AIDS prevalence rate for pregnant women attending public antenatal services is over 30%. And, by 2010, 19% of South African children will have experienced the death of one or both parents, half due to AIDS. In response to this crisis, the overarching objective of the proposed project is to conduct a short-term, longitudinal, multilevel study of 6000 7- to 10-year-olds and their parents in parent surrogate households in urban and rural South African communities in KwaZulu-Natal. The project consists of three specific aims:

AIM 1. Examine the associations between a) a set of major household risk factors and a set of adverse childhood experiences, and b) the occurrence and nature of adverse childhood experiences and child psychosocial, health and educational outcomes. AIM 2. Explore the degree to which selected factors at multiple levels moderate the influence of major household risk factors on adverse childhood experience, and adverse childhood experiences on key child outcomes. AIM 3. Test the effect of a major social policy innovation Conditional Cash Transfers on household and childhood risk factors (directly) and children’s well-being (indirectly). This project is a collaboration of researchers at New York University in the US and the Human Sciences Research Council in South Africa in cooperation with the South African government and the World Bank.

PUBLIC HEALTH RELEVANCE: The results of this study have two main implications for public health. First, one set of results will indicate whether Conditional Cash Transfers can improve the health, education and well-being of poor South African children in high-HIV/AIDS prevalence communities. Second, another set of results can inform the design of new public health and social policy strategies to support households in AIDS-affected communities.

Project Terms:

10-year-old; 16-year-old; Asidants; Acquired Immunodeficiency Syndrome; Adult; Adverse event; Affect; African; AIDS/HIV problem; Area; Behavioral Research; Cessation of life; Child; Child Care; Child health care; Childhood; Collaborations; Communities; Country; Critiques; design; Development; Economic Conditions; Economics; Educational Status; experience; Food; Goals; Government; Healthy; Health education; Health Policy; Health Status; House; Household; Household and Family; Human; Human Development; Improved; Income; generation; Institutes; Intervention; knowledge; Language; Letters; Life; Life Experience; Longitudinal analysis; Longitudinal Studies; Mortality; Vidal Statistics; Nature; New York; Orphan; Outcome; Parenting behavior; Parents; Personal Satisfaction; Policies; Poverty; Pregnant Women; Prevalence; Providence; psychosocial; public health medicine (field); public health relevance; randomized trial; Reporting; Research; Research Personal; Resources; response; Risk; Risk Factors; Rural; Schools; Science; Services; Social Development; Social Policies; Social Welfare; South Africa; Suicide; Testing; UNICEF; Universities; USAID; Withdrawal; Work; World Bank
SF424 (R&R) Application Guide for NIH and Other PHS Agencies

• Your bible
GRANT MECHANISMS
Selected NIH grant mechanisms

- **K-awards**
  - Research career development

- **R03**
  - NIH Small Grant Program

- **R21**
  - NIH Exploratory/Developmental Research Grant Award

- **R01**
  - NIH Research Project Grant Program
R03 Application Characteristics

• You may request:
  – Project period of up to two years
  – Budget for direct costs of up to two $25,000 modules or $50,000 per year
• The R03 cannot be renewed
• No preliminary data are required but may be included if available
• The Research Strategy may not exceed 6 pages
R03 Scope

• The common characteristic of the small grant is the provision of limited funding for a short period of time.

• Examples of the types of projects that ICs support with the R03 include the following:
  – Pilot or feasibility studies
  – Secondary analysis of existing data
  – Small, self-contained research projects
  – Development of research methodology
  – Development of new research technology
R21 Application Characteristics

• Application Characteristics
• You may request a project period of up to two years
• Combined budget for direct costs may not exceed $275,000
  – No more than $200,000 may be requested in any single year
• The R21 can not be renewed
• No preliminary data are required but may be included if available
• The Research Strategy may not exceed 6 pages
R21 Scope

• Exploratory, novel studies that break new ground or extend previous discoveries toward new directions or applications

• High risk high reward studies that may lead to a breakthrough in a particular area, or result in novel techniques, agents, methodologies, models or applications that will impact biomedical, behavioral, or clinical research
R01

- The R01 provides support for health-related research and development based on the mission of the NIH. R01s can be investigator-initiated or can be in response to a program announcement or request for application.
- The Research Project (R01) grant is an award made to support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing the investigator's specific interest and competencies, based on the mission of the NIH.
R01 Application Characteristics

- Not limited in dollars but need to reflect the actual needs of the proposed project
  - Modular applications are most prevalent with modules of $25,000, up to the modular limit of $250,000
  - U.S. applicants requesting more than $250,000 in annual direct costs and all foreign applicants must complete and submit detailed budget
  - Applications are generally awarded for 1 - 5 budget periods, each normally 12 months in duration.

- The Research Plan of an application for an R01 award must follow the instructions provided in SF424 (R&R) Application Guide, at http://grants.nih.gov/grants/funding/424/index.htm
Basic outline of an NIH grant –
The Research Plan a.k.a. The Science

- Specific Aims
- Research Strategy
- Human Subjects
- Gender and Minority Inclusion
- Inclusion of Children
- Literature Cited
Specific Aims

• Brief introduction
  – Statement of problem
  – Significance
  – Rationale for study

• Specific aims

• Overview of methods

• ONE PAGE MAX
The New Research Strategy

• Significance
• Innovation
• Approach
Significance

• Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.

• Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.

• Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.
Innovation

• Explain how the application challenges and seeks to shift current research or clinical practice paradigms.

• Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.

• Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.
Approach

• Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project.
• Include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
• Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
Approach

• If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.

• If there are multiple Specific Aims, then you may address Significance, Innovation and Approach for each Specific Aim individually, or may address Significance, Innovation and Approach for all of the Specific Aims collectively.
Preliminary Studies for New Applications

• This is your chance to show off and demonstrate how productive your team is
• Make sure the preliminary studies are relevant to the current proposal
• Discuss the PD/PI’s preliminary studies, data, and or experience pertinent to this application.
Preliminary Studies for New Applications

• Except for Exploratory/Developmental Grants (R21/R33), Small Research Grants (R03), and Academic Research Enhancement Award (AREA) Grants (R15), preliminary data can be an essential part of a research grant application and help to establish the likelihood of success of the proposed project.

• Early Stage Investigators should include preliminary data (however, for R01 applications, reviewers will be instructed to place less emphasis on the preliminary data in application from Early Stage Investigators than on the preliminary data in applications from more established investigators).
Research Strategy

- Summarize what we know
- Point out what we don’t know
- Highlight how YOUR study will fill those knowledge gaps
- Build a narrative that is easy for the reader to follow
- Do not assume the reader has the same depth of knowledge you do while at the same time don’t assume they know nothing
Research Design and Methods: Overview

- What design and rationale
- What population and rationale
- What will be done
- How it will be done
- Where will it be done
- What is the schedule
Research Design and Methods: Some Generic Elements

- Overview
- Population selection
- Data collection
- Data management
- Quality assurance/quality control
- Project administration
- Limitations
Research Design and Methods: Population selection

• What is the sampling frame
• Exposure assessment
• Disease assessment
• Inclusion and exclusion criteria
Research Design and Methods: Data collection

• Survey procedures
  – Face-to-face
    • Paper and pencil
    • CAPI
  – Telephone
  – ACASI
  – Web-based (e.g., Survey Monkey)

• Other data collection methods
  – Laboratory protocols
  – Direct observation
  – Focus groups
  – In-depth interviews
Research Design and Methods: Data collection

- Outcomes
- Exposures
- Confounders
- Other key covariates
Research Design and Methods: Data collection

- Standardized protocols
- Standardized training
- Standardized review
Research Design and Methods: Data management

- Entry and edit procedures
- Auditing
- Exploratory data analysis (EDA)
  - Creation of new variables
  - Transformation
Research Design and Methods: Quality assurance/control

- Training
- Supervisor and PI checks
- Reviews and audits of logs
- Double data entry
- Double logging
Research Design and Methods: Project administration

- Paper surveys
  - Handling paper
  - Tracking
- Data management hardware and software
- Documentation
- Securing
- Archiving
Research Design and Methods: Project management

- Management structure
  - Organizational structure
  - Roles
- Project tracking
  - Reporting
  - Anticipated milestones
- Project communications
  - Staff meetings
  - Meetings with external collaborators
  - Conflict management (especially for multiple PI applications)
- Advisory committees
  - Data Safety and Monitory Board
Research Design and Methods: Quantitative data analysis

• Data description
• Analytic strategy
  – Exploratory data analysis (EDA)
  – Bivariate
  – Modeling approaches
  – Controlling for confounding
  – Testing for interactions
• Statistical software
Research Design and Methods: Qualitative data analysis

• Data description
• Analytic strategy
  – Theoretical underpinnings
  – Approach
• Statistical software (if applicable)
• http://obssr.od.nih.gov/pdf/qualitative.pdf
Research Design and Methods: Limitations

• Bias
  – Selection bias
    • Potential sources
    • Consequences
    • Strategies to prevent/minimize
  – Information bias
    • Strategies to prevent/minimize
    • Validation studies
    • Adjustment methods
Research Design and Methods: Limitations

• Confounding
  – Potential confounders
  – Strategies for addressing confounding
    • Restriction
    • Matching
    • Stratification
    • Modeling

• Power
  – Assumptions
  – Adequacy of power
  – Consequences of error
  – Minimum detectable difference between groups
Research Design and Methods: Limitations

- External validity
  - Barriers to generalizability

- Feasibility
  - Population identification
  - Data collection
  - Costs
  - Alternative approaches
Human Subjects

• Involvement of human subjects
  – Rationale for selection
  – Inclusion/exclusion
  – Characteristics
• Sources of data
• Recruitment plan
• Consent process
• Potential risks and benefits
• Protecting against risks
• Risks v. benefits
Gender, Minority, and Children Inclusion

- Composition of proposed study group
- Rationale for selection
- Why exceptions
- Recruitment plan
Literature Cited

- Use consistent format for citations
- Does not count in page limitations
Budgets

- Personnel
  - PIs & co-Is
  - Research assistants
  - Interviewers
  - Analysts
- Consultants
- Equipment
  - ≥$5000
- Trainee costs
  - Tuition
- Supplies
  - Software, printing, computers
- Travel
  - Local
  - To conferences
- Patient care costs
- Alterations/ Renovations
- Other costs
  - Participant incentives
  - Laboratory testing
  - Phones
  - Postage
  - Animals
  - Publications
- Consortium/Contractual costs
  - Subcontracts to vendors or investigators at other institutions
Modular vs. Detailed budgets

- Modular budget
  - Request funds in lump sums of $25,000 intervals
  - Reduced detail for budget and justification
  - You will still need a detailed budget for the NYU internal system
Budget Justification

• **Purpose**: Helps answer the question: “Is the bang worth the buck?”

• **What is it?**: This section provides the rationale for all budget requests in terms of on and off-campus personnel, equipment, supplies, travel, rent, etc.

• No Page Limit

• Must be credible in the experience of the reviewers
NIH Grant Reviews

• Study the review criteria!!!!

• Find out who is on the study section
  – Look them up on Pubmed
  – Cite them, if appropriate
  – Identify potential conflicts of interest
## NIH Grant Scoring

<table>
<thead>
<tr>
<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
<th>Additional Guidance on Strengths/Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>1</td>
<td>Exceptional</td>
<td>Exceptionally strong with essentially no weaknesses</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
<td>Extremely strong with negligible weaknesses</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
<td>Very strong with only some minor weaknesses</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>Very Good</td>
<td>Strong but with numerous minor weaknesses</td>
</tr>
<tr>
<td>Medium</td>
<td>5</td>
<td>Good</td>
<td>Strong but with at least one moderate weakness</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Satisfactory</td>
<td>Some strengths but also some moderate weaknesses</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>Fair</td>
<td>Some strengths but with at least one major weakness</td>
</tr>
<tr>
<td>Low</td>
<td>8</td>
<td>Marginal</td>
<td>A few strengths and a few major weaknesses</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Poor</td>
<td>Very few strengths and numerous major weaknesses</td>
</tr>
</tbody>
</table>

**Non-numeric score options:** NR = Not Recommended for Further Consideration, DF = Deferred, AB = Abstention, CF = Conflict, NP = Not Present, ND = Not Discussed

**Minor Weakness:** An easily addressable weakness that does not substantially lessen impact

**Moderate Weakness:** A weakness that lessens impact

**Major Weakness:** A weakness that severely limits impact
TRICKS OF THE TRADE

A brief guide to NIH grantsmanship
Writing Style

• Clear
• Succinct
• Easy to follow
  – “Tell a story”
• Parallel construction
Signposting

- Tell your reader what you are going to tell them
- Tell them what you want to tell them
- Summarize what you told them
Incorporate the players

• Incorporate the research team throughout the grant
  – PI
  – Co-investigators
  – Consultants
  – Institutions and organizations
Describe the consent process

• Simply saying that there will be a consent form will likely not be enough
• Describe the complete consent process, including how to deal with those who refuse to participate
• Note proposed reading level of consent form and solutions for those who cannot read
• Note that you will obtain a certificate of confidentiality (as appropriate)
The Biosketch

• Personal Statement
  – Briefly describe why your experience and qualifications make you particularly well-suited for your role (e.g., PD/PI, mentor) in the project that is the subject of the application
  – This should be specific to each application

• Positions and Honors

• Peer-reviewed publications or manuscripts in press (in chronological order).
  – Limit of 15 preferred
  – 5 most relevant to the current application
  – 10 additional recent publications of importance to the field

• Research Support
  – List both selected ongoing and completed (during the last three years) research projects (Federal or non-Federal support). Begin with the projects that are most relevant to the research proposed in this application.
Remember grammar and spelling

- USE SPELL CHECK
- Use the grammar check
- Read over the grant before you send it out
- Ask someone to read it before you submit
- Read it out loud
Things to avoid

- Narrative that jumps around
- The grant doesn’t have a logical flow
- Not defining acronyms the first time you use them
- Not incorporating figures and tables into the narrative
Things to consider

- Figures and tables, when appropriate, are useful tools and they can break up the page for the reader.
- Too much white space or not using all the pages allowed often results in the knee-jerk critique “not enough detail”
  - On the other hand… a colleague who does rat studies submits R01s with fewer than 12 pages.
- Highlight “economies of scale”
The Page Limits…

- R03/R21: 1 page aims, 6 pages research strategy
- R01: 1 page aims, 12 pages research strategy

- In talking to colleagues, I have heard…
  - 2-3 pages of 12 page R01 devoted to significance and innovation, bulk to approach
  - Common reviewer complaint, “not enough detail”
Budgeting

• Need to think carefully about effort of each team member
  – If they are named on the budget, it’s a good idea to make sure they are named in the “science”
  – Make sure you have all the expertise needed to pull off the research

• Incentives can be cash, gift cards, objects, etc.
  – Depending on your population, you might want to budget for snacks

• Budget is not a part of the review criteria, but reviewers do see it

• It is typical for budgets to be cut (5-15%) if grant is awarded
Some “fatal” mistakes

- Waiting until the last minute
- Funding mechanism does not match the project
- Weak statistical plan or low power
- No back-up plans
- Lack of expertise in a key area
- Poor organization
- Weak or missing hypotheses and/or conceptual framework
- Lack of significance
- No innovation
- Too ambitious

Courtesy of Steffanie Strathdee and Tom Patterson at UCSD
### Funding success rates for selected NIH institutes, 2012

<table>
<thead>
<tr>
<th>NIH Institute/Center</th>
<th>Applications Reviewed</th>
<th>Applications Awarded</th>
<th>Success Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCI</td>
<td>7,972</td>
<td>1,085</td>
<td>13.6%</td>
</tr>
<tr>
<td>NEI</td>
<td>994</td>
<td>296</td>
<td>29.8%</td>
</tr>
<tr>
<td>NHLBI</td>
<td>5,208</td>
<td>768</td>
<td>14.7%</td>
</tr>
<tr>
<td>NIA</td>
<td>2,020</td>
<td>314</td>
<td>15.5%</td>
</tr>
<tr>
<td>NIAAA</td>
<td>908</td>
<td>167</td>
<td>18.4%</td>
</tr>
<tr>
<td>NIAID</td>
<td>5,416</td>
<td>1,255</td>
<td>23.2%</td>
</tr>
<tr>
<td>NICHD</td>
<td>3,554</td>
<td>443</td>
<td>12.5%</td>
</tr>
<tr>
<td>NIDA</td>
<td>1,886</td>
<td>399</td>
<td>21.2%</td>
</tr>
<tr>
<td>NIDDK</td>
<td>3,055</td>
<td>606</td>
<td>19.8%</td>
</tr>
<tr>
<td>NIEHS</td>
<td>1,213</td>
<td>177</td>
<td>14.6%</td>
</tr>
<tr>
<td>NIMH</td>
<td>2,702</td>
<td>584</td>
<td>21.6%</td>
</tr>
<tr>
<td>NIMHD</td>
<td>141</td>
<td>14</td>
<td>9.9%</td>
</tr>
<tr>
<td>NINDS</td>
<td>3,592</td>
<td>702</td>
<td>19.5%</td>
</tr>
<tr>
<td>NINR</td>
<td>623</td>
<td>81</td>
<td>13%</td>
</tr>
<tr>
<td>FY Totals</td>
<td>51,313</td>
<td>9,032</td>
<td>17.6%</td>
</tr>
</tbody>
</table>
## Funding success rates for selected funding mechanisms, 2012

<table>
<thead>
<tr>
<th>Type of Grant</th>
<th>Activity</th>
<th>Applications Reviewed</th>
<th>Applications Awarded</th>
<th>Success Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>New R01</td>
<td></td>
<td>24,637</td>
<td>3,662</td>
<td>14.9%</td>
</tr>
<tr>
<td>New R03</td>
<td></td>
<td>2,875</td>
<td>572</td>
<td>19.9%</td>
</tr>
<tr>
<td>New R21</td>
<td></td>
<td>13,743</td>
<td>1,932</td>
<td>14.1%</td>
</tr>
<tr>
<td>New K01</td>
<td></td>
<td>522</td>
<td>168</td>
<td>32.2%</td>
</tr>
</tbody>
</table>
Figure 1. Average Age of Principal Investigators with MD, MD-PhD, or PhD at the time of First R01 Equivalent Award from NIH, Fiscal Years 1980 to 2011
1R01-Equivalent grants, New (Type 1)
Success rates, by career stage of investigator
Percentage of NIH R01 Principal Investigators Age 36 and Younger and Age 66 and Older (Fiscal Years 1980 to 2010)
Final thoughts

• Writing grants in a vacuum (e.g., alone) is not always productive. Even if you are the main writer…
  – Conversations about the science with colleagues will help shape your thinking
  – A second pair of eyes is invaluable
    • If someone can’t read the whole document, ask them to focus on a specific section

• Talk to the project officer, they are there for clarification about the funding announcement and may be able to give some info on what’s “hot” and what’s “not”