Obtaining NIH Funding as an Engineer

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The National Institutes of Health (NIH)

- Really a collection of separate institutes and centers, each with its own interests and priorities. You must actually target one (or more) specific institutes with your proposal.
- Some are particularly relevant for engineering research:
  - National Institute of Biomedical Imaging and Bioengineering
    - Most engineering research is submitted here, but it’s almost always better (in terms of success rate) to target a specific application and institute
  - National Eye Institute
  - National Heart, Lung, and Blood Institute
  - National Institute of Child Health and Human Development
  - National Institute on Deafness and Other Communication Disorders
  - National Institute of General Medical Sciences
  - National Cancer Institute
  - and many more…
What gets funded by the NIH?

- Most medical research in the United States is funded by the NIH
  - Much larger budget than the NSF; NSF wants to fund high-risk science, and will decline a proposal that looks too “translational”
  - DOD, FDA, CDC, and private foundations also fund medical research
- NIH funds important, translational medical problems
  - Not the right venue to propose new ideas that might be useful for medical problems in the future
  - Problem should be motivated by a clinician (i.e., surgeon, cardiologist, nurse, etc.)
  - You must have a clinical collaborator to be successful!
  - Clinicians know the problems and the current standard of care, but their ideas for how to solve the problem might not be that well conceived; this is where the engineers come in.
  - Should have preliminary evidence that the proposed solution is likely to work. The project should typically be low-risk, high-reward.
Types of NIH Awards

• **R01**
  – “Standard” research project; 3-5 years
  – No budget limits; max of $250k per year (direct costs) with a modular budget (discussed in a future slide); need permission for more than $500k in any given year

• **R21**
  – 1-2 years; $275k total (direct costs)
  – Encourages new exploratory and developmental projects. Sometimes used for pilot/feasibility studies.
  – Still typically requires preliminary data to be successful.

• **R03**
  – 1-2 (or sometimes 3) years; $50k per year (direct costs)
  – Pilot/feasibility studies, collection of preliminary data for an R01, self-contained project, development of technology, etc.
Types of NIH Awards

- **R41/R42: Small business technology transfer (STTR)**
  - Used to get research from universities into industry and/or fund early-stage innovation
  - PI must be affiliated (somehow) with the business
  - A substantial portion of the budget must go to the university
  - Three-phase structure
    - Phase I: Feasibility study; 1 year; $150,000 (direct costs)
    - Phase II: Full R&D; 2 years; $1,000,000 (direct costs)
    - Phase III: Commercialization (cannot use STTR funds)

- **R43/R44: Small business innovative research (SBIR)**
  - Can involve universities (or not), but PI must be from the business
  - Three-phase structure
    - Phase I: Feasibility study; 6 months; $150,000 (direct costs)
    - Phases II and III are the same as with the STTR
Mandatory Structure of an NIH proposal

- **Research Strategy**
  - The main document of the proposal
  - 12 pages for an R01, 6 pages for R21 and R03
  - Bibliography doesn’t count against page limits

- **Specific Aims**
  - 1 page technical summary of the proposal

- **Project Summary**
  - Maximum 30-line summary (which is less than half a page), written for an well-educated broad audience

- **Project Narrative**
  - 1-2 sentence summary that explains the impact of your project (i.e., why it warrants tax dollars) to the widest possible audience

- **Cover Letter**
  - Helps assign your proposal to the right reviewers
Research Strategy

• Significance
  – This is the first section, which introduces the medical problem.
  – This section should be taken very seriously, and should be authored primarily by the clinical collaborator.
  – Let’s be clear, you should be talking about:
    • Reducing morbidity (improving health and quality of life)
    • Reducing mortality (i.e., death)
    • Reducing cost (to individuals and to society)
  – If you can’t make a strong case for at least one of the items above, you should seriously consider if your proposal is worth pursuing.
  – Use this section to make the “high-reward” of the project clear.
  – This section should use the jargon of the medical field. It should not look like it is written by an engineer.
  – Approximately 1-3 pages
  – Avoid discussing your proposed solution to the problem
Research Strategy

- **Innovation**
  - This is the second section, which introduces the proposed solution to the problem.
  - What is the proposed solution?
  - How does the proposed solution solve the problem?
  - How are prior solutions to the problem insufficient, and how is your solution able to overcome what they have not?
  - This is a good place to talk about preliminary results (including unpublished results) than indicate that the proposed solution has a high likelihood of success.
  - You’re not really talking here about what work you are going to do with the award, but rather, you’re selling the idea itself.
  - Approximately 1-2 pages in a 6-page Research Strategy
  - Approximately 1-5 pages in a 12-page Research Strategy
Approach

- This is the third and final section, which describes the work that will be done with the support of the award, following the Specific Aims.
- You really should have completely thought through the work that you will do, with a timeline of events and milestones, and describe them with as much detail as you can fit within the page limits.
- Often appropriate to include preliminary results in this section as well.
- Use this section to make the “low-risk” of the project clear.
- Include “Potential Pitfalls and Alternative Strategies” throughout the document. Make it clear you have a back-up plan.
- Include clear metrics to measure success.
- NIH loves statistics. Consider including a biostatistician in the proposal, including in the proposal preparation.
  - University of Utah Study Design and Biostatistics Center
  - http://medicine.utah.edu/ccts/sdbc/
Specific Aims

- This is a one-page stand-alone summary of the work to be done, meant to be read by the reviewers and program manager, which also serves as a type of contract of the results you will deliver.
- Typically begins with a brief summary of significance and innovation of the project (approximately 0.25-0.5 page).
- Then describes the projects specific aims; typically 1 (maybe 2) for small projects, and 1-3 for R01s).
  - These are the projects major contributions (what you will learn)
  - The specific aims should be formulated and worded such that you are guaranteed to be successful if you do the work.
    - For example, not “our device will prevent blood clots”, but rather, “we will quantify the reduction in blood clots using our device”.
  - Should ideally be independent of each other, but related
  - Within the specific aims, list the tasks (what you will do).
- Include a short summary of the contribution of the project.
Cover Letter

• The cover letter is short and sweet. It tells the administrative staff at NIH where to assign the proposal
  – The project’s title should include both the significant medical problem that will be addressed and the proposed research
  – Must provide the funding announcement to which you are submitting
  – Must indicate one or more institutes
  – Must indicate one or more study sections (a.k.a. scientific review groups) with the expertise to review the proposal
  – The NIH provides a standard format in the text.

• List of standing study sections can be found online.
  – Search using keywords
  – Find the best one or two study sections for your proposed research
  – You may not get what you request (they may know better)
  – This is possibly more important than selecting the correct institute.
Example Cover Letter

Dear Center for Scientific Review Staff,

This cover letter accompanies the submission of an application titled “Robot-assisted Tele-echocardiography to Diagnose Newborn Congenital Heart Defects” in response to PA-13-303 (Exploratory/Developmental Research Grant [R21] program).

Please assign this application to the following:
Institutes/Centers
  National Institute of Child Health and Human Development – NICHD
  National Heart, Blood, and Lung Institute – NHBLI
Scientific Review Groups
  Bioengineering, Technology, and Surgical Sciences – BTSS
  Special Emphasis Panel – SBIB (12) Cardiovascular and Surgical Devices
  Medical Imaging – MEDI
Passing On Some Good Advice

• I once heard some good advice about writing NIH proposals, that I think applies to proposal writing more generally.
• There are four steps in the proposal. Don’t move on to the next step until you’ve effectively completed the current step.
• Step 1: Convince us of the importance of the problem.
  – Proposals often fail here, and all of the (potentially good) engineering ideas that follow are pointless.
• Step 2: Convince us that there is a good solution to the problem.
• Step 3: Convince us that you are qualified and have a good plan to succeed in the solution to the problem.
• Step 4: Convince us that you are uniquely qualified.
  – A unique team, a unique skill-set, unique hardware, or unpublished results that give you some advantage over your peers
• Think how this fits with Significance, Innovation, and Approach
Budgeting Time and Money

- NIH has a big budget, and they are serious about using their resources to solve important medical problems as rapidly as possible. This philosophy pervades their view of your proposal.
- Always budget the maximum amount of time
  - You are proposing a cutting-edge problem, and if they fund your proposal it means they want you to solve it, not run out of time with more work left to do.
  - The ability to obtain follow-up funding is contingent upon the results of your first award. You need the maximum amount of time to get those publications accepted.
  - Don’t think you can ingratiate yourself to reviewers or program managers by budgeting fewer years, making your proposal less expensive to the NIH than your competitors.
Budgeting Time and Money

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  – You are proposing a cutting-edge problem, and if they fund your proposal it means they want you to solve it, not run out of money with more work left to do.
  – Don’t think you can ingratiate yourself to reviewers or program managers by budgeting less than the max, making your proposal less expensive to the NIH than your competitors.
  – Unless you are a senior researcher with a proven track-record with the NIH, use a modular budget and its budget caps (next slide)

• Remember that NIH budget caps are given in direct costs. NIH will pay any additional overhead (a.k.a. Facilities and Administrative costs) that is calculated on those direct costs.
The Modular Budget

- The modular budget is the standard and preferred budgeting method (preferred by NIH, and also benefits you as well)
- A module is $25,000 of direct costs
- Each award type has a maximum number of modules allowed in any given year
- With the modular budget, you don’t provide a budget justification
  - You don’t have to specify how you are going to spend the money!
  - Saves you a lot of effort, and doesn’t let the reviewers start knitting your budgeting decisions
  - NIH has basically decided in advance how much money it takes to be successful on a given-sized project
- You must still provide a “Personnel Justification” document that describes the effort of all of the senior personnel
- Unless you have a track-record with NIH, use a modular budget!
Budgeting Effort of the Investigators

• Budgeting for NIH is not like budgeting for NSF
  – NSF cares about funding students, and other outreach activities
  – With NSF, it is typical to budget between 0.5-1 month of effort per investigator
  – With NSF, you don’t want your budget to be too “top heavy”

• NIH only cares about the research getting done
  – For each investigator, try to budget at least 1 month of effort per investigator (if you think about it, that’s only about 1 day every two weeks)
  – The PI should budget more (at least 2 months for an R01)
  – Budgeting no students is no problem (can be all postdocs and senior personnel), but grad students are also okay
• NIH is constantly changing the format of their biosketch. Make sure you know the most current version.
• This is the place to explain the expertise of the team members (nice that its outside of the page limits of the main proposal).
• In addition to standard items like education and employment history, and past and current funding support…
• Each biosketch begins with a personal statement, where the investigator gets to explain (in first person) why he/she is interested and qualified in this project, and what his/her role will be.
• Includes up to five “Contributions to Science”, which are broad research areas that the investigator has contributed to.
  – Each area can include up to four publications.
• No long, complete list of publications like in a CV
Understanding the Scoring System

• You will get detailed reviews from a small number of reviewers, written before the study section, that provide a detailed breakdown of what they like and don’t like about your proposal.

• Then the study section gets together and discusses your proposal. After the discussion, each panelist gives an overall score to your proposal, with 1 being perfect, and 9 being worthless.
  – The scores are averaged, and then multiplied by 10.
  – Thus, 10 is a perfect score, and 90 is the worst possible score.
  – This is not a ranking of proposals, but rather, a stand-alone score independent of other proposals’ scores.

• A percentile score (relative to others) is also given sometimes.

• A score of less than 20 is typically competitive for funding.

• A score of less that 50 could still be competitive in a resubmission, if it’s handled well.
Resubmitting Your Proposal

• You can resubmit a revised version of a failed proposal as many times as you like, but…

• You only get one official “resubmission”. After that, your proposal is again counted as a new submission.

• In a resubmission, you get an extra page to respond to the concerns of the reviewers

• Study sections have slow turn-over, so many of the reviewers will be the same people who reviewed the first proposal
  – Very different from NSF

• In this way, NIH proposals are somewhat like journal papers
  – If the reviewers liked the basic idea the first time, and you can address all of their concerns, you’ll have a good chance of getting funded on the resubmission

• You only get one resubmission, so take the revision seriously
Additional Resources

- **RePORTER**
  - Search engine to see what a program has been funding and what study sections reviewed the grants.
  - You can search by institution, PI, text, award mechanism, etc.

- **Matchmaker**
  - Copy and paste your abstract and the search engine will help you find funded grants with similar topics.

- **Success Rates**
  - Lots of data is available by institute and mechanism.
  - This can be used to determine competitiveness of the program and help identify application strategies with higher likelihood of success.

- **Institute Strategic Plans**
  - Most of the institutes specify their priorities and their paylines for the upcoming funding cycle.