National Institutes of Health Funding Workshop:

"How to fund your NIH R01"

Presented by the Office of Sponsored Programs
& the Office of Faculty Development and Diversity

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Contents:

- Broad Overview
- NIH Institutes
- NIH Centers
- Types of grant and Standard Deadline Dates
- NIH Review Process
  - Submission and CSR
  - Review, Scoring and Rankings
- General Structure of the Proposal
- Timing
- Networking with NIH Staff
- Budget Related Considerations
- NIH vs NSF
- K awards
- Useful Links

Broad Overview:

NIH will fund any research that can be justified as being to the benefit of the NIH mission, which is "to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability". Your research has to be in some way relatable to health and disease.

NIH Institutes

National Cancer Institute (NCI)
National Eye Institute (NEI)
National Heart, Lung, and Blood Institute (NHLBI)
National Human Genome Research Institute (NHGRI)
National Institute on Aging (NIA)
National Institute on Alcohol Abuse and Alcoholism (NIAAA)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
National Institute of Biomedical Imaging and Bioengineering (NIBIB)
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
National Institute on Deafness and Other Communication Disorders (NIDCD)
National Institute of Dental and Craniofacial Research (NIDCR)
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
National Institute on Drug Abuse (NIDA)
National Institute of Environmental Health Sciences (NIEHS)
National Institute of General Medical Sciences (NIGMS)
National Institute of Mental Health (NIMH)

National Institute on Minority Health and Health Disparities (NIMHD)
National Institute of Neurological Disorders and Stroke (NINDS)
National Institute of Nursing Research (NINR)
National Library of Medicine (NLM)

NIH Centers
Center for Information Technology (CIT)
Center for Scientific Review (CSR)
Fogarty International Center (FIC)
National Center for Advancing Translational Sciences (NCATS)
National Center for Complementary and Integrative Health (NCCIH)
NIH Clinical Center (CC)

Types of grant and standard deadline dates:
There are two types of both R01 and R21 grants offered by the NIH, Parent (standard) R01/R21 and Special Emphasis R01/R21. Most researchers start by writing a Parent R01 proposal, and move on to writing a special emphasis proposal, but it doesn't have to be done in that order. These special emphasis RFAs are important, because if your research fits well into their funding mission, it might be easier to get a good review and therefore, get funded.

Parent R01 deadlines are offered three times per year, February 5th, June 5th and October 5th for new proposal submissions, and March 5th, July 5th and November 5th for both renewal or resubmission proposals. New and renewal/resubmissions for the Parent R21 grants follow the same pattern but with February 16th, June 16th and October 16th, or March 16th, July 16th and November 16th deadlines, respectively. The specific institute and study section to which the parent R01 or R21 grant will be submitted should be carefully selected by the researcher. The wrong study section or institute for your research could be the difference between getting your proposal funded, and not. Deadlines for special emphasis funding opportunities will be specific to that particular grant opportunity, and should be checked on a case-by-case basis. The institute and study section for these opportunities have been pre-selected, and it is important for researchers to give NIH feedback on potential new areas for funding research.

NIH Review Process

Submission and CSR:
The NIH review process can be confusing for those who haven't taken part in the grant review process. NIH has a budget of around $32 billion annually, most of which goes to extramural research programs, although some does go to intramural programs. Each Institute has a specific disease focus, whereas NIGMS is more focused on basic research relatable to human health.
Grants submitted to NIH are actually reviewed by the Center for Scientific Review (CSR), which is a completely separate entity from the institutes, and they organize study sections and the review process, and assign the grant to a study section to review. Grants that will ultimately be assigned to different institutes or centers might all get reviewed by the same study section, if they have a similar focus. You can ask for your grant to be assigned to a particular study section, and it is very important that you choose the study section you request your grant be reviewed by very carefully, as the reviewers that score your grant can mean the difference between it being funded, or not. It is also important that you choose an institute and study section in which your research is a good fit. This can be mentioned in the cover letter of your grant.
Grants are reviewed by faculty peers, these are mainly faculty from US institutions, but can be from Canada and Europe also. The grant is general reviewed by a primary reviewer, and two secondary reviewers, who provide preliminary scores for the grant, and present the grant to the study section. The entire study section then scores the grant. Each reviewer might review 8-10 grants per study section, and therefore, will only be able to champion 1 or 2 grants which they believe should be funded. Therefore, your grant has to capture the imagination of the reviewer and really make them want to champion it during the study section meeting. Only the top 50% of grants scored are discussed at the meeting, the rest get triaged and do not get discussed. If the grant is discussed, it will be given a percentile score, so

for example the 11th percentile is the score below which 11% of the scores will be found of grants that were discussed.

<u>Before you submit to a study section</u>:
- Reach out to the scientific review officer and ask if your idea/specific aims fits with their study section mission
- Reach out to the program officer and ask if their institute is interested in this research
- If you have a competitor, exclude them as a reviewer for your grant
- Look up who are the permanent members of the study section

Review, Scoring and Rankings:

<u>Reviewing</u>: As mentioned, each reviewer will receive 8-10 grants to review, and will review based on the five subscore categories; significance and scientific premise, innovation, investigator, approach and discussion of relevant biological variables, environment. <u>Significance</u>: Is the work important? Is there a (clinical) need that needs to be addressed? Is the research studying a fundamental new mechanism? Is it based on strong scientific premise? <u>Innovation</u>: Is the research addressing new and novel, or is it merely an incremental step from previous research? Are most innovative techniques available being used? <u>Investigator</u>: Is the PI an accomplished investigator? Teams of investigators, rather than just one PI, are beginning to be more favorably reviewed, although be wary of losing new investigator status by teaming up on multiple PI grant applications. The PI must show the reviewer that they have recruited a great team to do the research. Good to include letters from all collaborators, have they worked as a team successfully before? Engineers should almost always include a biologist on the grant. Biologists should consider letters from pathologists or a bioinformatics researcher to enhance their grant- include letters. <u>Approach</u>: What is the research trying to accomplish? Will the experiments outlined address the specific aims? Must include controls and other experimental parameters. Are relevant biological variable such as sex considered? Must read like an interesting story, rather than a list of protocols- this section is all about capturing the reviewer's imagination. <u>Environment</u>: At Cornell, the environment scores should be very strong, given the resources available. Include letters from centers, core facilities etc. Include all facilities on Cornell campus available to the project and relevant to the research. Include list of memberships, faculty collaborations, seminar series, etc. Significance and Innovation are reviewed relatively briefly. The most critically reviewed part of the grant is the approach. Different reviewers might weight different sections more highly.

<u>Study section and scoring</u>: The primary reviewer will summarize the grant to the whole study section, followed by a period of 15-20 minutes of discussion. Every member of the 20-30 person study section will score the grant. Each reviewer gives a score, three reviewers, so three scores, and then the members of the study section will all score the grant, based upon the primary reviewer's presentation of the grant to the study section. They can score out of range, but generally will stick within the range set by the three reviewers, so if the grant has captured the imagination of the primary or secondary reviewer, they will want to champion it in this setting by making strong points about why it should be funded. If not, they will not fight for the grant, might give it a bad score, and then all the other members of the study section will be free to vote in the lower range, and it might receive bad scores as a result. Resubmissions should always address the reviewer comments from the previous submission.

<u>Study section members</u>: The standing roster of permanent study section members is available online on the CSR website. It is a good idea to look at the standing members, and get an idea of the types of expertise on the study section. If you do not know anyone's name on the roster, it's probably the wrong place to send your grant for review. Ad hoc members are not revealed until after the study section has met. To increase the chance of being selected to sit as an ad hoc member of a study section, PIs can write to the SRO and volunteer, or if they know someone on the study section, can ask them to introduce them. More early-career faculty are being asked to serve on study sections. Anyone from Cornell will have a natural conflict with a PI from Cornell, and will be asked to leave the room during a review of a Cornell grant. The same goes for close collaborators.

What if your grant gets assigned to the wrong study section? The PI can try contacting the scientific review officer to explain that they feel it is not a good fit and should be assigned elsewhere, however it is usually very difficult to get the proposal assigned elsewhere. Sometimes, this works to the advantage of the PI, especially if there are people on that study section to review their proposal. There are also satellite

study sections for those that are very popular and inundated with proposal submissions. If the proposal is a resubmission, and the original submission went to a study section that was not appropriate, the PI could try submitting the grant as a new submission, rather than as a resubmission, as the chances of getting assigned to the same study section with a resubmission are high (be sure to change the name).

General Structure of the Proposal:

Administrative requirements: Take care of these first, and get them to your department research administrator or to OSP so that you can focus on the science. Make sure you have the correct version of the forms, if in doubt ask OSP.

General proposal considerations: Get advice on proposal outline from colleagues. Get hold of some of their successful proposals and read them.

Cover Letter: The PI should focus on the cover letter, as it tells NIH which institute and study section to assign the proposal to, and why. The PI should also document any interactions with the program officer about this proposal, and should list any reviewers they wish to exclude here.

Abstract: Very straightforward section of the proposal, anyone should be able to read it and understand the meaning, if not the scientific implications. This will be the part of the proposal that will be published for the general public to read, so PIs should be wary about how much detailed information they include. Remember, any competitors will have access to this abstract.

Project Narrative: 2-3 sentences about why this proposal is important, and its relation to the NIH mission. Should be very general and not technical.

Specific Aims: This is a good place to begin the writing- even a long way in advance of putting the rest of the proposal together. This will be read by the most reviewers. Include a background and why the research is important, then 2-3 specific aims. At the end of each aim, the PI should detail why they are doing this and why it is important. The aims should not be dependent on one another, but they should be complementary. Don't include references. Finish with a summary paragraph.

Research Strategy:
- Significance- Why is the research important, why do the fundamental mechanisms need to be investigated to further understanding of the research. PI should sell themselves, but not oversell. They should think hard about how to advertise the research.
- Approach- start with a rationale, and include expected outcomes. Include an alternative approach in case the research doesn't go as expected.
- Preliminary data- Can be included anywhere in the proposal that the PI thinks it is important. Could be in significance section.
- Figures- no standard number required. Although some reviewers like not to have a wall on text on the page. As long as the figure used makes a point relevant to the proposal. Describe what is in the figure, do not make it too small. Visually enhances the proposal.
- Scientific Rigor and Reproducibility- Very important that this section is good. Reviewers are being asked to consider this in their reviews. Can address in a section at the end of the research strategy, or on a case by case basis throughout the proposal. Things to include: How the PI will validate the data; include details of repeated experiments; explain using fresh cells lines every so often to maintain integrity; ensure the use of correct compounds/antibodies/mouse lines etc.; ask multiple people to repeat key results; how the results are robust and reliable; how bias will be eliminated.
- Sex and other biological variables- This is a new scorable category that needs to be addressed. For example, does the disease you are studying have a sex bias? Are your models acknowledging this. If you use animals and are only using a single sex (all males e.g.) then unless it is scientifically justified, this will result in lower scores.

Timing:

Should a PI apply early for their first R01, or wait for good preliminary data? If the PI feels good about their preliminary data, and have talked with mentors both inside and outside their department, there's no reason to wait. However, it's not recommended to submit a grant the PI isn't confident about or happy with. Regardless of timing, it is important for the PI to demonstrate they can deliver by having a strong

track record of grant results and/or publications, mostly this will stem from the postdoc and early faculty positions. Do not submit weak applications, as reviewers tend to remember these and might hold it against the PI in subsequent submission reviews. New investigators are reviewed together, and are given a small break in terms of preliminary data. If the project is not sufficiently developed to apply for an R01, the PI could consider applying for an R21 instead. Not as much preliminary data required, use as segue to write a larger grant. Some institutes don't fund R21s.

Networking with NIH staff:

How do investigators go about building a strong relationship with Program Officers or reviewers?
- PIs should not share the grant with a standing study section member or reviewer directly- this is a terrible conflict and the reviewer is advised to report this.
- Instead, PIs can invite reviewers to give seminars at their institution as a chance to meet them, and get to know them, and for the reviewer to get to know the PI and their science. Can talk generally about their research, but should not discuss their grants specifically.
- The relationship with a program officer is a very important one. It's a good idea to contact them prior to submitting to an institute. This should be mentioned in the cover letter when submitting a grant- that the PI has discussed with the program officer and they think the research is a good fit with the program. This will increase the chance of the grant being sent to that institute. Some institutes have a little wiggle-room when it comes to budgets, so even if the PIs grant is not within the pay line, the program officer, if they think the research is good and a fit with the program, can champion that grant and argue for that one to be funded. Therefore, cultivating a strong relationship with the program officer is advisable.
- Do not invite the program officer to Cornell, unless it's for a specifically program-related event. This is a conflict for them, and they will not be able to accept.
- Program officers attend conferences in their program area, so that is always a good place to meet them and present your research.

Budget related considerations:

What salary should a new investigator request? How much salary a PI budgets for their effort is really dependent upon where they are in their career. The standard/average is probably around 25%. The salary should match how much effort you are putting into the grant.
Are graduate students still being allowed on NIH grants? No changes so far.
Generally, the budget should match what the PI is proposing. If the PI needs a postdoc or grad student (or both) to complete this project, they are justified in asking for one.
Does the size of the budget affect the fundability? The budget is a non-scorable review item. So the reviewers will be asked if they have any issues with the budget that is proposed. If a detailed budget is requested, they might reduce it down to modular.
Ask for as much as is justifiable, NIH will always cut the budget, however obscene budgets might affect the reviewer's state of mind when reviewing.

NIH vs NSF:

NIH proposals must have a clear link to human health, however NSF proposals must not be related to human health at all. Generally NSF budgets are smaller than NIH. There are clear grantsmanship differences, so if a PI is used to applying to one, they should seek advice before switching and applying for the other.

K awards:

Why consider K-awards? A PI might want to consider submitting a K award if they don't feel ready to submit an R award in their career. Can search for currently funded K-awards by specific institute using the NIH project reporter. Can find research relevant to the PI's own, what kind of K-awards are funded by each institute, and what research has already been funded.

<u>How are K-awards different</u>? K awards are largely about funding the investigator. There are extra sections included in the proposal about career plan, training, potential, mentoring etc. that are not included in an R proposal. Less emphasis on preliminary data. PI can find out which K-award would be good for them using the "K-wizard" decision tree on the NIH website.
Things to consider:

- K awards can be 3, 4 or 5 years
- Depending on the K award, all or a large portion of salary may be covered; research costs vary depending on the K but are less than an R01
- Indirect costs (F&A) differ by award; check the specifics of the award you are considering, and get advance approval from your institution
- Start R01 planning early in K award, so there's more time to transition
- Mentors are needed on some K awards,
- In planning your transition from K to R01, make sure you've established high productivity and clear independence; collaborations with senior investigators are fine to continue as long as the overlap in expertise is minimal and you are the clear lead.
- NIH has a student loan repayment program that junior faculty should consider if applicable. https://www.lrp.nih.gov/
- Speak to previous K award recipients if they are willing (can be found on the NIH Reporter).

<u>Useful Links:</u>

Search for FOAs: http://grants.nih.gov/funding/index.htm
NIH overview: https://www.nih.gov/about-nih/who-we-are
Organization of centers and institutes: https://www.nih.gov/about-nih/who-we-are/organization
Center for Scientific Review: http://public.csr.nih.gov/aboutcsr/Pages/default.aspx
CSR meeting and roster links: http://public.csr.nih.gov/RosterAndMeetings/Pages/default.aspx
NIH contact info: https://www.nih.gov/sites/default/files/about-nih/nih-quickfinder.pdf
Parent R01 RFA: http://grants.nih.gov/grants/guide/pa-files/PA-16-160.html
Parent R21 RFA: http://grants.nih.gov/grants/guide/pa-files/PA-16-161.html
NIH Reporter: https://projectreporter.nih.gov/reporter.cfm
Career awards: http://archives.nih.gov/asites/grants/03-26-2015/training/careerdevelopmentawards.htm
K wizard decision tree: http://archives.nih.gov/asites/grants/03-26-2015/training/careerdevelopmentawards.htm