Navigating the NIH:  
*Grants Process Overview & the R01*

Hiten Madhani,  MD,  PhD  
Professor, Dept of Biochemistry and Biophysics  
Sr. Investigator, Chan-Zuckerberg BioHub  
madhanilab.ucsf.edu  
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Agenda

• Who cares about research?
• Funding trends over the last 20 years
• NIH Institutes
  o Types, Funding Priorities
• Where to Start
  o Good grantsmanship
• Grant review process
• The R01
  o Writing, good presentation, common errors
• NIH resources
America: Who Cares About Research?

SO, SANITY AND LOGICAL PROGRESSION

WHO CARES?
In your view, how important is it for President Trump to assign a high priority to putting health research and innovation to work to assure continued medical progress?
Who is funding?
Support of biomedical research at US Universities

2016 Federal Investment in Medical and Health R&D, by Funding Agency

Total 2016 Federal Expenditures: $37.6 billion

- National Institutes of Health: 81.0%
- Other Federal Agencies: 2.0%
- Tradition Funding Agencies:
  - Department of Defense: 5.6%
  - Centers for Medicare and Medicaid Services: 3.7%
  - National Science Foundation: 2.0%
  - Veterans Administration: 1.7%
  - Agency for Healthcare Research and Quality: 1.1%
  - Food and Drug Administration: 1.0%
  - Centers for Disease Control and Prevention: 0.9%
  - Patient-Centered Outcomes Research Institute: 0.8%
Congressional Support for NIH Funding

- NIH’s funding capacity has been restored to its pre-sequestration level (FY 2012) through these budget increases.
- In both FY 2016 and FY 2017, Congress raised the NIH budget by $2 billion.

With the FY 2016 budget increase alone, NIH was able to award 832 more research project grants.
NIH Research Funding Portfolio Ratios

- Clinical Research 15%
- Translational Research 25%
- Basic Research 60%

Basic scientific research…provides scientific capital.

Vannevar Bush, 1945
What are the trends for R01 funding?
UCSF’s NIH Funding by Year, 1992-2016

- UCSF is the top public recipient of NIH research funding for the last 6 consecutive years
Number of Research Project Grants

Source: NIH Data Book [http://report.nih.gov/nihdatabook/index.aspx](http://report.nih.gov/nihdatabook/index.aspx) and supplemental tables available in RePORT
Number of Competing Awards (with First-time R01)

Applications (with First-time R01)

Source: NIH Data Book [http://report.nih.gov/nihdatabook/index.aspx](http://report.nih.gov/nihdatabook/index.aspx) and supplemental tables available in RePORT
Success Rates

Source: NIH Data Book [http://report.nih.gov/nihdatabook/index.aspx](http://report.nih.gov/nihdatabook/index.aspx) and supplemental tables available in RePORT
Success Rates for New (Type 1) Applications

Source: NIH Data Book [http://report.nih.gov/nihdatabook/index.aspx](http://report.nih.gov/nihdatabook/index.aspx) and supplemental tables available in RePORT
Average Grant Size

Source: NIH Data Book http://report.nih.gov/nihdatabook/index.aspx and supplemental tables available in RePORT
TELL ME MORE.

Understanding the NIH
National Institutes of Health (NIH)

NIH is the steward of medical and behavioral research for the Nation

Mission: to acquire new knowledge to help prevent, detect, diagnose, and treat disease and disability …

… from the rarest genetic disorder to the common cold
27 Institutes and Centers (IC)

Each with a different:

- Director
- Mission & priorities
- Budget
- Funding strategy
Funding Opportunities

- “A publicly available document by which a Federal agency makes known its intentions to award discretionary grants or cooperative agreements, usually as a result of competition for funds”
- **Advertised through**
  - Grants.gov
  - NIH Guide for Grants and Contracts
- **Issued by**
  - Each IC
  - “Parent” announcements span the breadth of the NIH mission, include many ICs
### Types of Funding Opportunity Announcements (FOA)

<table>
<thead>
<tr>
<th>Type of FOA</th>
<th>Description</th>
</tr>
</thead>
</table>
| **Program Announcements (PA, PAR, PAS)** | • Highlights areas of focus  
• Usually ongoing (3 years)  
• Often use standard receipt dates |
| **Requests for Applications (RFA)**   | • Narrowly defined scope  
• Usually single receipt date  
• **Set aside funds**  
• IC usually convenes review panel |
| **Parent Announcements**             | • Type of program announcement  
• Generally span the breadth of NIH mission  
• By activity code (R01, R03, etc)  
• For “investigator initiated” or “unsolicited” research ideas |
## Example: NIAAA

<table>
<thead>
<tr>
<th>Category</th>
<th>URLS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institute</td>
<td><a href="http://www.niaaa.nih.gov/">http://www.niaaa.nih.gov/</a></td>
</tr>
<tr>
<td>Director</td>
<td><a href="http://www.niaaa.nih.gov/about-niaaa/our-staff/directors-page">http://www.niaaa.nih.gov/about-niaaa/our-staff/directors-page</a></td>
</tr>
<tr>
<td>Funding Priorities</td>
<td><a href="http://www.niaaa.nih.gov/about-niaaa">http://www.niaaa.nih.gov/about-niaaa</a></td>
</tr>
<tr>
<td></td>
<td><a href="http://www.niaaa.nih.gov/research">http://www.niaaa.nih.gov/research</a></td>
</tr>
<tr>
<td>FOAs</td>
<td><a href="http://www.niaaa.nih.gov/grant-funding/funding-opportunities">http://www.niaaa.nih.gov/grant-funding/funding-opportunities</a></td>
</tr>
<tr>
<td>Who to contact</td>
<td>Check the “resources for applicants” and the FOA for contact info</td>
</tr>
</tbody>
</table>
NIH Institute: What is the best fit for you?

• Where is your Mentor’s/Sponsor’s funding from?
• Where would you like to build a research career?
• Might your grant fit in one or more institutes?
• If yes to above question, is one institute more/less competitive? Has more/less money?
• Check out currently funded projects in the research area/institute you are interested in:
  • [http://projectreporter.nih.gov/reporter.cfm](http://projectreporter.nih.gov/reporter.cfm)

Ask the institute!!
NIH Funding: Types of Grants

• Pre-doctoral
  o F30, F31, R36; Administrative Supplement

• Postdoctoral
  o F32, T32

• Early Career
  o Ks (K01, K08, K22, K23, K99/R00)

• Mid-Late Career
  o R-grants (R21, R34, R01); U01; P30; K-grants (K05, K24)
When are applications due?
<table>
<thead>
<tr>
<th>Activity Codes</th>
<th>Program Description</th>
<th>Cycle I Due Date</th>
<th>Cycle II Due Date</th>
<th>Cycle III Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>R01</td>
<td>Research Grants</td>
<td>February 5</td>
<td>June 5</td>
<td>October 5</td>
</tr>
<tr>
<td></td>
<td>New</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>U01</td>
<td>Research Grants - Cooperative Agreements</td>
<td>February 5</td>
<td>June 5</td>
<td>October 5</td>
</tr>
<tr>
<td></td>
<td>New</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>K series</td>
<td>Research Career Development</td>
<td>February 12</td>
<td>June 12</td>
<td>October 12</td>
</tr>
<tr>
<td></td>
<td>New</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R03, R21, R33, R21/R33, R34, R36, U34, UH2, UH3, UH2/UH3</td>
<td>Other Research Grants and Cooperative Agreements</td>
<td>February 16</td>
<td>June 16</td>
<td>October 16</td>
</tr>
<tr>
<td></td>
<td>New</td>
<td></td>
<td></td>
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<tr>
<td>R15</td>
<td>Academic Research Enhancement Award (AREA)</td>
<td>February 25</td>
<td>June 25</td>
<td>October 25</td>
</tr>
<tr>
<td></td>
<td>All - New, renewal, resubmission, revision</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>R01</td>
<td>Research Grants</td>
<td>March 5</td>
<td>July 5</td>
<td>November 5</td>
</tr>
<tr>
<td></td>
<td>Renewal, resubmission, revision</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>U01</td>
<td>Research Grants - Cooperative Agreements</td>
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<td>March 16</td>
<td>July 16</td>
<td>November 16</td>
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<tr>
<td></td>
<td>Renewal, resubmission, revision</td>
<td></td>
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</tr>
<tr>
<td>F Series Fellowships (including F31 Diversity – NOT-OD-17-029)</td>
<td>Individual National Research Service Awards (Standard)</td>
<td>April 8</td>
<td>August 8</td>
<td>December 8</td>
</tr>
<tr>
<td></td>
<td>New, renewal, resubmission, revision</td>
<td></td>
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</tbody>
</table>

[Grant Submission Dates](http://grants.nih.gov/grants/funding/submissionschedule.htm#elec)
## NIH Funding Review Dates


<table>
<thead>
<tr>
<th>Period of Application Due Dates</th>
<th>Cycle I</th>
<th>Cycle II</th>
<th>Cycle III</th>
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<tbody>
<tr>
<td>Jan 25 – May 7</td>
<td>May 25 - Sept 7</td>
<td>Sept 25 - Jan 7</td>
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<table>
<thead>
<tr>
<th>Scientific Merit Review</th>
<th>Cycle I</th>
<th>Cycle II</th>
<th>Cycle III</th>
</tr>
</thead>
<tbody>
<tr>
<td>June - July</td>
<td>Oct - Nov</td>
<td>Feb - Mar</td>
<td></td>
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</table>

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<thead>
<tr>
<th>Advisory Council Round</th>
<th>Cycle I</th>
<th>Cycle II</th>
<th>Cycle III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aug or Oct</td>
<td>January</td>
<td>May</td>
<td></td>
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</tbody>
</table>

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<thead>
<tr>
<th>Earliest Project Start Date</th>
<th>Cycle I</th>
<th>Cycle II</th>
<th>Cycle III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sept or Dec</td>
<td>April</td>
<td>July</td>
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</table>
BUT... WHERE DO I EVEN START??
Does it address an important problem?
Will scientific knowledge be advanced?
Does it build upon or expand current knowledge?
Is it feasible …
  o to implement?
  o to investigate?
Good Grantsmanship

- Contact NIH program staff early
- Assess IC interest & “goodness of fit”
- Are there related FOAs?
- Searching web sites is good start … *but follow up with personal contact*
- Send a 2 – 3 page concept paper to a program contact
Good Grantsmanship

- Collaborate with other investigators
  - Fill gaps in your expertise and training
  - Add critical skills to your team
  - Support for multidisciplinary research projects
  - Consider the Multiple-PI Model
- Talk to NIH program contact if the project involves multiple PIs

grants1.nih.gov/grants/multi_pi
Good Grantsmanship

- Ask a colleague to review your draft
  - Someone who doesn’t know what you intend to do
  - Don’t ask your best friend!

- Your draft reviewers need to understand
  - What you intend to do
  - Why you believe it's important
  - Exactly how you are going to do it

  Leave enough time to make revisions
Who to Contact When?

**Pre-Submission**

Contact YOUR GRANTS OFFICE, and grant.gov, or NIH eRA Help for issues related to submission.

Contact PD/PO for IC scientific mission relevance of your research, and advice on grant mechanism, IRG selection and/or revision; and GMS for budget related issues.

**Pre-Review**

Application in

Contact SRO for any review related issues such as changing IRG, sending in supplements, indicating conflicts etc.

**Post-Review**

Peek Review

Contact PD/PO for revision and funding.

Once funded, contact PD/PO for scientific relevant issues and GMS for process and/or policy issues.
Electronic Submission & Requirements

• Learn about the electronic application submission process **well before** the application due date
• Complete/renew required registrations (Start now!)
  - Investigators must register in the eRA Commons
• Understand your institutional processes and timelines for grant-related activities
• Develop the application
  - Carefully read the funding opportunity
  - Look at previous recent applications (some sections don’t need re-invention)*

*UCSF library has many useful templates
What Determines Which Grants Are Funded?

- Impact Score—Scientific merit
- Program considerations
- Availability of funds
Grant Review Process
Review Process for a Research Grant

1. Initiates Research Idea
2. Submits Application
3. Center for Scientific Review
   Assign to IC & IRG/ Study Section
4. Study Section
   Review for Scientific Merit
5. Institute
   Evaluate for Relevance
6. Advisory Councils and Boards
   Recommend Action
7. Institute Director
   Takes final action
8. Allocates Funds
9. Conducts Research

National Institutes of Health

Research Grant Application
School or Other Research Center
The Grant Review Process

- Applications must be submitted from a recognized institution

- Each application has two independent reviews within NIH: “Dual Review”

- Funding goes to the investigator's home institution not the investigator
The Grant Review Process

**Dual Review:**

1. **Study Section:**
   - Scientific merit
   - Written review & score

2. **Institute Council:**
   - Significance, programmatic merit
   - Approval for funding
The Grant Review Process

**Center for Scientific Review (CSR):**

- Independent unit within NIH
  - separate from Institutes
- Administers review panels (Study Sections)
- Receives & assigns applications:
  - to Study Sections for review
  - to Institutes for funding

http://www.csr.nih.gov/welcome.htm
Assignment to CSR Study Sections

Applications are assigned to Integrated Review Groups (IRGs) for review. IRGs are clusters of scientifically-related study sections

• The IRG assignment is based on specific referral guidelines for each IRG

• Each of the 20 IRGs within CSR has 5 - 8 standing study sections
Peer Review in CSR

- CSR Study Sections are managed by a Scientific Review Administrator (SRA) who is a professional, usually at the PhD level, whose scientific background is close to the expertise of the study section.

- Each CSR standing study section has 12 - 24 members who are primarily from academia.

- As many as 60 - 100 applications are reviewed at each study section meeting.
Criteria For Selection of Peer Reviewers

- Demonstrated Scientific Expertise
- Doctoral Degree or Equivalent
- Mature Judgment
- Work Effectively in a Group Context
- Breadth of Perspective
- Impartiality
- Interest in Serving
- Adequate Representation of Women and Minority Scientists
The Study Section

Members:

• working scientists (~15-20)
• one member serves as Chair

Scientific Review Administrator (SRA)

• NIH (CSR) staff person
• assigns grants to reviewers, collates reviews

Meetings:

• 1-2 days, 3 times per year
How Study Sections Work

- Application is assigned to institute, and to IRG, then to a Study Section
- SRO scans abstracts (~100); determines needed expertise; invites ad hoc members
- SRO assigns applications to members for primary or secondary review or for reading
- Applications are distributed to members for reading and preparation of review; reviewers assign criteria scores and *preliminary overall impact/priority score (1-9)*
- At study section meeting, SRO summarizes procedures, conflict of interest sanctions; identification of “streamlined” applications (~50%)
Peer Review: Process

- The SRO prepares an order of review that *clusters* New Investigator (NI) applications, Early Stage Investigator applications (ESIs) and *clinical* applications if feasible.

- NI and ESI applications are identified for reviewers so there can be appropriate review in context of career stage.

- Expectations of preliminary data and publication track record supposedly *less* than for established investigators.
NIH Study Section Meeting

- Each proposal is assigned to
  - a primary reviewer
  - a secondary & usually a tertiary reviewer
  - can have 1-3 “readers”

- Each reviewer has about 10 reviews to write
- Everyone is free to discuss/comment
- Everyone scores every proposal (ad hoc scores don’t count)
Sequence of Review

- Moderated by Chair
- Reviewers indicate degree of enthusiasm
- Primary & secondary reviewers present
- Tertiary reviewer comments
- Open discussion
- Applications scored
- SRA writes summary of discussion
- NIH "Peer Review Revealed" Video

https://www.youtube.com/watch?v=fBDxI6l4dOA
Peer Review: Evaluation Criteria

- Review of applications based on NIH standard review criteria
  - Significance “Strong and sustained impact on the field”
  - Investigators
  - Innovation
  - Approach (including Preliminary Data)
  - Environment

- Initiative specific review criteria, when applicable
  - Human subjects inclusions and protections
  - Animal welfare
  - Type of application (i.e., resubmission, renewal, revision)
  - Biohazards

- Different criteria for training-related applications
What is not scored:

- Budget and period support
- Select agent research
- Applications from foreign organizations
- Resource sharing plans

These criteria do not affect the overall impact, but reviewers must comment or provide text for an administrative note.
### Study Section Scores assigned

<table>
<thead>
<tr>
<th>Overall Impact Score</th>
<th>Guidance on weighing strengths and weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High Impact</strong></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Exceptional</td>
</tr>
<tr>
<td>2</td>
<td>Outstanding</td>
</tr>
<tr>
<td>3</td>
<td>Excellent</td>
</tr>
<tr>
<td><strong>Moderate Impact</strong></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Very Good</td>
</tr>
<tr>
<td>5</td>
<td>Good</td>
</tr>
<tr>
<td>6</td>
<td>Satisfactory</td>
</tr>
<tr>
<td><strong>Low Impact</strong></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Fair</td>
</tr>
<tr>
<td>8</td>
<td>Marginal</td>
</tr>
<tr>
<td>9</td>
<td>Poor</td>
</tr>
</tbody>
</table>

Non-numeric score options: NR = Not Recommended for Further Consideration, DF = Deferred, AB = Abstention, CF = Conflict, NP = Not Present.
NIH Review Process

Scoring of NIH grant applications

- Impact Score is not merely a mean/average of the Criterion Scores (entirely up to reviewers!)
- Only assigned reviewers provide Criterion Scores; Range 1 to 9.
- All reviewers (not in conflict) provide Impact Scores; Range 1 to 9.
- Application’s Impact Score is the mean of all non-conflict reviewers’ scores x 10; Range 10 to 90.
Priority Scores and Percentile Rank

- Priority Scores assigned by Study Sections based on average of all reviewers scores (not ad hocs)

- **Percentile Rank** assigned afterwards to normalize scoring across study sections and over time

- **Funding determined by percentile rank and institute’s funding plan.**
1) Study Section Review

Approved Applications
Receive Percentile Scores

1st John Doe (Biochem. SS)
2nd Your Grant (Oncology SS)
13th Stancel (Genetics SS)
27th Jane Doe (Micro. SS)

Etc.

“Streamlined”
Not Recommended for Further Consideration

2) Institute Funding Decision

National Cancer Institute
(Budget from Congress)

1) Your Grant $ $
2) John Doe $ $
3) Stancel $ $
4) Jane Doe $ $

Payline
Etc.
Etc.
Etc.
- 
- 
-
NIH Review Process

After first-level review meeting

• Impact/Priority Scores are recorded within 48 hours in eRA Commons

• Summary statements (essentially unedited critiques) are viewable in eRA Commons 4 to 6 weeks after the review meeting and include the following:
  o “Resume and Summary of Discussion” section that briefly highlights the main points discussed during the review meeting, including major strengths and weaknesses
  o Criterion Scores given by assigned reviewers
  o Overall Impact/Priority Score and percentile ranking
  o Budget recommendations
  o Administrative notes
NIH Review Process

After first-level review, Contact Your Program Officer

• As soon as you receive your summary statement, contact your Program Officer. Find his or her name in the Commons and at the top of your summary statement.

• Ask your Program Officer
  o About the probability of funding
  o Whether he or she (or a representative) attended the review meeting as an observer and can give you additional insight into the discussion
NIH Review Process

Not Discussed (ND) applications

• About half of the applications are ND.
• Review meeting focuses discussions on the most competitive applications, based on preliminary scores.
• If any reviewer disagrees with a decision not to discuss an application, the group will review that application.
• ND applications:
  o Do not receive an Overall Impact Score or a “Resume and Summary of Discussion” summary.
  o Do receive a summary statement with Criterion Scores and critiques from assigned reviewers.
Second-level review meeting

- Conducted by the National Advisory Council or Board for the assigned Institute/Center
- Review meeting focuses on discussions on the most competitive applications, based on preliminary scores.

**Activities open to the public:**
- Approval of new program initiatives and concept clearances
- Consideration of policy issues

**Activities closed to the public:**
- Assessment of the quality of first-level review
- Concurrence with or modification of Integrated Review Group action
- Designation of application as “High” or “Low” program priority
Get to the Right Study Section!!!

• Make sure your application goes to the right study section*

• Complete the PHS Assignment Request Form
  - suggest IC and review group assignment*
  - Outline key expertise needed for appropriate review
  - do not name specific reviewers

* Consult with Program Officer
PHS Assignment Request Form

Funding Opportunity Number: 

Funding Opportunity Title: 

Awarding Component Assignment Request (optional)

If you have a preference for an Awarding Component (e.g., NIH Institute/Center) assignment, please use the link below to identify the most appropriate assignment then enter the short abbreviation (e.g., NCI for National Cancer Institute) in "Assign to/Do Not Assign To Awarding Component" sections below. Your first choice should be in column 1. All requests will be considered; however, locus of review is predetermined for some applications and assignment requests cannot always be honored.

Information about Awarding Components can be found here: https://grants.nih.gov/grants/phs_assignment_information.htm#Awarding Components

Assign to Awarding Component: 1 2 3

Do Not Assign to Awarding Component: 

Study Section Assignment Request (optional)

If you have a preference for a study section assignment, please use the link below to identify the most appropriate study section then enter the short abbreviation for that study section in "Assign to/Do not Assign to Study Section" sections below. Your first choice should be in column 1. All requests will be considered; however, locus of review is predetermined for some applications and assignment requests cannot always be honored.

For example, you would enter "CAMP" if you wish to request assignment to the Cancer Molecular Pathobiology study section or enter "ZRG1 HDM-R" if you wish to request assignment to the Healthcare Delivery and Methodologies SBIR/STTR panel for informatics. Be careful to accurately capture all formatting (e.g., spaces, hyphens) when you type in the request.

Information about Study Sections can be found here: https://grants.nih.gov/grants/phs_assignment_information.htm#Study Section

Assign to Study Section: 1 2 3

Only 20 characters allowed

Do Not Assign to Study Section: 1 2 3

Only 20 characters allowed
Most Common Reasons Given for Not Receiving Funds

- Rationale for hypothesis or methods not sound or not supported by preliminary data
- Unfocused or superficial research plan
- Aims do NOT address hypothesis
- Flaws in experimental approaches
- Models not relevant to human situation
- Unrealistically large amount of work proposed
- Work not new or original (*lack of appreciation of published relevant work*)
- Lack of experience in essential methods
- Insufficient experimental detail
- Serious risks to human subjects or use of animals
Panel Discussion: The NIH Peer Review Process

Moderated by Elise Riley, PhD, Professor, Department of Medicine

- Hana El-Samad, PhD, Associate Professor, Biochemistry & Biophysics
- Hani Goodarzri, PhD, Assistant Professor, Biochemistry & Biophysics
- Hiten Madhani, MD, PhD, Professor, Biochemistry & Biophysics
- Sheri Weiser, MD, Associate Professor, Medicine
R01 Grant Basics
R01 – Research Project Grants

- Investigator-initiated
- Discrete, specified research
- Awards renewable
  - Up to 5 years (usually 3–5 years)
  - If > $500K/year, must request NIH Center for Scientific Review (CSR)/Institute Program Director approval to submit

- NIH allows for original and up to one resubmission that addresses the reviewers critical comments
- No limit to number of original submissions
Successful Grant Writing Requires:

Good is not Good enough
BE OUTSTANDING!

- Outstanding
  - Science
  - Partnership
  - Presentation
- Clear Communication

*If writing is not your forte, Get Help!*
Contact the NIH program officer

- Do NOT “Cold Call!”
- Send an Email to request setting up a time to talk
- Email should include:
  - Name of program(s) of interest
  - Your NIH-formatted Biosketch (assesses your eligibility)
  - Specific Aims Page (assesses if your concept aligns with NIH IC mission)
- General questions to ask:
  - Is your Institute interested in funding research like this?
  - Does this fall within a priority area of research for your institute?
  - Are others currently funded doing similar work?
  - How can I improve this concept?
- Several dates/times available
# Page Limit Summary

<table>
<thead>
<tr>
<th>Section of Application</th>
<th>Page Limits</th>
</tr>
</thead>
<tbody>
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<td>Introduction to resubmission or revision applications</td>
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Writing an R01

- Write Specific Aims section and discuss with mentor or an NIH grantee
- Give yourself four weeks to write first draft
- Full draft to mentor one month before submission date
  - Read and follow the instructions (electronic 424)
  - Prepare budget with budget person
- Write for a general scientific audience
- Simple is better
- Repetition is good
You must have simple testable hypothesis that is supported by preliminary data
  - Study Sections are conservative
  - No preliminary data = No award

Demonstrate medical significance

Rationale, limitations of methods, controls, and back-up plans are critical

Details of methods are unimportant (boring) but make sure the reviewers know you know the methods and say so

Get collaborators and consultants- strong letters
Specific Aims

- **The most critical page** in the application
- **It is a one-page summary of the application**
  - Describe Overall Impact expected
  - Why is this problem significant?
  - What are the exciting preliminary data?
  - What hypotheses do the data support?
- **Simple list of your Aims is good**
  - Be general
  - Avoid long (laundry) list of things you are going to do
  - 2-3 Specific Aims is sufficient (Focus: must fit together)
Research Strategy

- Assume you are not writing for an expert (but look at the study section ROSTER)
- Emphasize general medical importance and then specific importance of your topic
- Avoid jargon
- Discuss controversies in the area
- Avoid selective citation of the literature
- Make your story interesting - make the reviewer want to read more!
- Correct English grammar and attention to typographical errors are important.
- Reviewers like a “pretty” application.
Preliminary Data

• Show primary data for critical methods
• Make figures or tables readable
• Progress Report- for renewals
  o Restate Aims (avoid laundry list)
  o Publication list **MUST** be very strong. No productivity - no grant. Selectivity of journals matters.
• Convince reviewer that you can do what you propose
Approach (Methods)

- Do you have the right tools and experience?
- Is this the right model system/preparation?
- Are there adequate controls?
- Are you discussing the pitfalls and alternatives?
- Avoid details (volumes, components of buffers)
- Show a time line - reviewers like them
Good Presentation

3 Simple Steps:

- Read the application instructions carefully
- Read the application instructions carefully
- Don’t forget …

Read the application instructions carefully!

http://enhancing-peer-review.nih.gov/restructured_applications.html
Good Presentation

• Title
  • Capture essence of goals and objectives

• Abstract
  o Present your project Concisely
  o State significance Clearly
  o State Hypotheses, Research Problem, Solution
  o Methods and Rationale

• Write direct, active text: Read aloud.
Organize the Research Strategy to answer 4 essential questions:

- What do you intend to do?
- Why is the work important?
- What has already been done?
- How are you going to do the work?
Address Scored Review Criteria

- **Significance:** Does the study address an important problem? How will scientific knowledge be advanced? If aims are achieved, will it have a strong and sustained impact on the field?

- **Investigator:** Is the investigator appropriately trained? Are there the right collaborators in place?

- **Innovation:** Are there novel concepts or approaches? Are the aims original and innovative?

- **Approach:** Are design and methods well-developed and appropriate? Are problem areas addressed?

- **Environment:** Does the scientific environment contribute to the probability of success? Are there unique features of the scientific environment?
## Alignment of Application Format with Scored Review Criteria

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<th>Scored Review Criteria</th>
<th>Application</th>
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<td>Environment</td>
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Good Presentation

• Provide well-focused research plan
• Keep specific aims simple … *and specific*
• Link hypotheses to specific aims
• Explain method chosen to test every hypothesis
• Don’t wander from the main theme
• A conceptual model can clarify ideas
Good Presentation

- Be realistic … not overly ambitious
- Discuss potential problem areas
- Discuss possible solutions
  - Explain rationale for your decisions
- Be explicit
- Reviewers cannot read your mind …

*Don't assume they know what you intend*
Prepare a reviewer-friendly application

- Be well organized and clear
- Use logical transitions between sections
- Add section headings -- major and minor
- Make tables and figures easy to view
- Eliminate all **mispelings** and **type-O's**
Good Presentation

Prepare a reviewer-friendly application

- Be well organized and clear
- Use logical transitions between sections
- Add section headings -- major and minor
- Make tables and figures easy to view
- Eliminate all misspellings and typo’s
Elements of an Outstanding Grant Application

- New or original ideas
- Pilot data (essential for R01/ less critical for Fs and Ks)
- Focused, incisive research plan
- Knowledge of published relevant work
- Experience in the essential methodology
- Future directions and contingency plans
R01 Common Errors

- Not discussing literature that is contrary to your ideas
- Not discussing strengths and limitations of your data - don’t let reviewer do it for you!
- Proposing too much for 3 or 5 years
- Common criticisms:
  - “This Specific Aim could serve as an entire grant in and of itself”
  - “Research is unfocused”
  - “Study is overambitious”
  - “Not clear investigator has needed experience”
R01 Common Errors (cont’d)

- Lack of relationship to disease (non-GM institutes)
- Methodology over Biology is not good
- Descriptive vs Hypothesis-driven
  - “Looking at” (bad) vs “testing” (good)
  - “Fishing expedition” (bad)
- No biostatistical support
  - Sample size (power) calculations for animal or human studies
  - Inadequate control group
Not Funded! Now What?
Options for Non-Funded Research

- NIH allows for original and up to one resubmission that addresses the reviewers critiques
- There is no limit to original submissions
- Before a resubmission can be done, the applicant must have received the summary statement from original review
- Email Program Officer indicated top of summary statement to set up time to discuss your application and any next steps
Response to Critiques
When you Resubmit an Application

• Resubmission must include response to reviewer comments

• Make it easy for reviewer to find your “answers.”

• Misunderstandings are your fault - if they missed a key fact in a figure or table, maybe it wasn’t clear enough.

• Be diplomatic and positive (most reviewer’s comments are good). Don’t argue with reviewers.

• Avoid tone that says “You (the reviewer) don’t know anything about this area.”

• Strive to publish and cite your preliminary data—publications help revisions more than anything else.

• Avoid overstating your data.
Don’t Give Up!!

- Initial failure is common
- Understand which parts of the application process are under your control
- Learn from a failed submission and succeed - majority do
  - Study criticisms in Summary Statement
  - Discuss with program to decide if problems are repairable
  - Attend diligently to each criticism
  - Keep a positive tone and attitude
Panel Discussion: Lessons Learned About Preparing an R01

Moderated by Elise Riley, PhD, Professor, Department of Medicine

- Hana El-Samad, PhD, Associate Professor, Biochemistry & Biophysics
- Hani Goodarzri, PhD, Assistant Professor, Biochemistry & Biophysics
- Hiten Madhani, MD, PhD, Professor, Biochemistry & Biophysics
- Sheri Weiser, MD, Associate Professor, Medicine
NIH Guide for Grants and Contracts

- Official publication listing NIH funding opportunities and policy notices
- Published weekly
- Lists grants and contracts
  - Request for Applications (RFA)
  - Program Announcements (PA) (& PAR, PAS)
  - Request for Proposals (RFP)
Research Portfolio Online Reporting Tool (RePORT)


- A Searchable database of federally supported biomedical research -- Replaces C.R.I.S.P.
- Access reports, data, analyses, expenditures, results of NIH supported research activities
- Identify, Analyze IC(s) research portfolios, funding patterns, funded investigators:
  - Identify areas with many or few funded projects
  - Identify NIH-funded investigators and their research
  - Identify potential mentors/collaborators
grants1.nih.gov/grants/oer.htm
Funding Opportunities and Notices

The NIH Guide for Grants and Contracts is the official publication for NIH medical and behavioral research grant policies, guidelines and funding opportunities. Definitions and More Information...

Search the NIH Guide for:
- Active RFAs (Requests for Applications)
- Active PAs (Program Announcements)
- Recent Notices (Released in Last 12 Months)
- Inactive & Active Announcements (use Advanced Search)

With Announcement # or Keywords: (Optional) Search Advanced Search

Browse Active Funding Opportunities
- Requests for Applications (RFAs)

Browse Recent Policies and Guidelines
- Notices (Released in last 12
Grant Writing Tips Sheets

Many NIH Institutes put out guides and tip sheets on their Web sites. These guides can be useful resources. Here are just a few.

- All About Grants - Including Grant Application Basics, How to Plan a Grant Application and How to Write a Grant Application.
- Applying for an NHGRI Grant
- Choosing an Appropriate NIH Funding Instrument and Funding Mechanism (MS Word - 209 KB)
- NIH Grants Information CD (PDF - 51 KB)
- Peer Review Guidelines and Information
- Peer Review Meetings - Meeting dates, descriptions, rosters, guidelines, etc.
- Preparing Grant Applications
- Quick Guide for Grant Applications
- Quick Guide for the Preparation of Grant Applications (Complementary and Alternative Medicine)
- SBIR/STTR Policy and Grantsmanship Information
- Tips for New NIH Grant Applicants
- Writing a Grant

Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint or RealPlayer files, see Help Downloading Files.
These "All About Grants" tutorials help biomedical investigators, especially new ones, plan, write, and apply for the basic NIH research project grant, the R01. Our advice comes from the experience of NIAID staff, including former NIH grantees, and should be considered as opinion only. Differing opinions may exist.

We do not repeat instructions in the [PHS 398 grant application kit](https://www.niaid.nih.gov/ncn/grants/). Before preparing an application for an NIH grant, read all instructions, and follow the directions.

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Find more information on the [main Grants Funding page](https://www.niaid.nih.gov/ncn/grants/), including:

- [Annotated R01 Grant Application](https://www.niaid.nih.gov/ncn/grants/)
- Quick Facts on Research Grant Applications
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