“Words of Wisdom from a NIH Research Training Officer”

Discussion at UCSF of Research Training Programs and Grantsmanship

Shawn Gaillard, Ph.D.
March, 2018
Agenda

Part I:
  – Overview of NIH
  – Research Training Programs

Part II:
  – Grantwriting:
    How to Apply for Funding
Part I

– Overview of NIH

– NIH Funded Programs
National Institutes of Health

• NIH roots trace back to 1887 in one room lab to examine passengers on arriving ships for clinical signs of infectious diseases

• Conduct research in our own labs (intramural), supports biomedical research at labs across the U.S. and globally (extramural)

<table>
<thead>
<tr>
<th>Intramural:</th>
<th>Extramural:</th>
</tr>
</thead>
<tbody>
<tr>
<td>We do research;</td>
<td>We support res;</td>
</tr>
<tr>
<td>~1K PIs on campus</td>
<td>~300K Researchers,</td>
</tr>
<tr>
<td></td>
<td>2.5K univ, med, other</td>
</tr>
</tbody>
</table>
NIH is the steward of medical and behavioral research for the Nation. Our mission is science in pursuit of knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability.

Annual Budget
>$30 Billion
Office of the Director

NCI  NEI  NHLBI  NIA  Fogarty  NIAAA  NIAID  NIAMS

NICHDI  NCAM  NIMHD  NCATS  NHGRI  NIDA  NIDCD  NIDCR

NIDDK  NIBIB  NIEHS  NIGMS  NINR  NIMH  NINDS  NLM

CC  CSR  CIT
<table>
<thead>
<tr>
<th>Institute</th>
<th>Budget</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCI</td>
<td>$5.7B</td>
</tr>
<tr>
<td>NIAID</td>
<td>$4.9B</td>
</tr>
<tr>
<td>NHLBI</td>
<td>$3.2B</td>
</tr>
<tr>
<td>NIGMS</td>
<td>$2.6B</td>
</tr>
<tr>
<td>NIDDK</td>
<td>$2.0B</td>
</tr>
<tr>
<td>NIA</td>
<td>$2.0B</td>
</tr>
<tr>
<td>NINDS</td>
<td>$1.8B</td>
</tr>
<tr>
<td>NIMH</td>
<td>$1.6B</td>
</tr>
</tbody>
</table>

Total NIH Budget (enacted): $34.2B
NIAID Mission

Conduct and support basic and applied research to better understand, treat and ultimately prevent infectious, immunologic and allergic diseases

Unique Dual Mandate:

Maintain and “grow” a robust basic and applied research portfolio in microbiology, infectious diseases, immunology and immune-mediated diseases

Respond rapidly to Emerging and re-emerging disease threats

New/Improved Interventions
NIAID Mission – “Maintain”

Life Expectancy for 20-Year-Old Newly Diagnosed with HIV, 1980s vs Today

1980s (no ART) | 1-2 years from AIDS diagnosis

Today (on ART) | ~53 years

Source: JL Marcus et al., JAIDS, 2016
NIAID Mission

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Respond rapidly to Emerging and re-emerging disease threats

New/Improved Interventions
NIAID Mission – “Respond”

Ebola
NIAID Mission – “Respond”

Mosquito-Borne Zika Virus
Baby Born w/Microcephaly
In addition to conducting research in our own labs (intramural) and supporting research at laboratories around the world (extramural), the NIH mission also includes **training the next generation of scientists**
Career Stages for NIH Funding

- Institutional Training Grant (T34)
- Institutional Training Grant (T32)
- Individual NRSA Fellowship (F31, F30)
- Institutional Training Grant (T32)
- Individual NRSA Fellowship (F32)
- Loan Repayment Programs (L30, L40)
- Pathway to Independence Award (K99/R00)
- Mentored Research Scientist Development Award (K01)
- Mentored Clinical Scientist Development Award (K08)
- Mentored Patient-Oriented RCDA (K23)
- Mentored Quantitative RCDA (K25)
- Independent Scientist Award (K02)
- Midcareer Investigator Award in Patient-Oriented Research (K24)

Graphic represents a small sample of NIH funding mechanisms available.
NRSA: “Fs” and “Ts”

https://researchtraining.nih.gov/programs/training-grants

- National Research Service Award – 1974 legislation

- Individual (apply to NIH) “F” – Fellowships:
  - F30 (MD/PhD)
  - F31 (Predoctoral)
  - Diversity F31
  - F32 (Postdoctoral)

- Institutional (apply at your school) “T” – Training:
  - T35 (short-term)
  - T32 – Predoctoral and Postdoctoral
Loan Repayment Programs

https://www.lrp.nih.gov/

- Designed to recruit and retain highly qualified health professionals into biomedical or behavioral research careers.

- LRP - support up to $35,000 annually of a researcher's qualified educational debt in return for a commitment to engage in NIH mission-relevant research.

NIH National Institutes of Health
Division of Loan Repayment

Apply for an LRP Award?
Take a look at what happens next

Apply
Award
Renew
Research Career “K” Development

- Launched in 1957
- More than 20 different types of “Ks” offered since inception

GOAL:
Foster Research Independence (e.g., R01)
2011 NIH study of mentored, individual K programs

Compared to unfunded applicants, K awardees received more subsequent NIH research support and were more likely to apply for—and receive—R01s

2017 NIAID K Assessment – Similar Results

Ks Work!
Our NIAID K outcomes slated to be posted on our website soon.

** NIH K Mechanism Program Name**

<table>
<thead>
<tr>
<th>NIH K Mechanism</th>
<th>Program Name</th>
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<tbody>
<tr>
<td>K01</td>
<td>Mentored Research Scientist</td>
</tr>
<tr>
<td>K02</td>
<td>Independent Research Scientist</td>
</tr>
<tr>
<td>K05</td>
<td>Senior Research Scientist</td>
</tr>
<tr>
<td>K07</td>
<td>Academic</td>
</tr>
<tr>
<td>K08</td>
<td>Mentored Clinical Scientist Research</td>
</tr>
<tr>
<td>K12</td>
<td>Clinical Scientists Institutional</td>
</tr>
<tr>
<td>K18</td>
<td>Research Career Enhancement</td>
</tr>
<tr>
<td>K22</td>
<td>Career Transition</td>
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<tr>
<td>K23</td>
<td>Mentored Patient-Oriented Research</td>
</tr>
<tr>
<td>K24</td>
<td>Midcareer Investigator Award</td>
</tr>
<tr>
<td>K25</td>
<td>Mentored Quantitative Research</td>
</tr>
<tr>
<td>K26</td>
<td>Midcareer Investigator in Biomed</td>
</tr>
<tr>
<td>K43</td>
<td>Emerging Global Leader</td>
</tr>
<tr>
<td>K76</td>
<td>Emerging Leaders</td>
</tr>
<tr>
<td>K99s/R00s*</td>
<td>Pathway to Independence Programs*</td>
</tr>
</tbody>
</table>

* Open to non-US citizens

## NIAID Ks


<table>
<thead>
<tr>
<th>K</th>
<th>Program Name</th>
<th>Category</th>
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</thead>
<tbody>
<tr>
<td>K22</td>
<td>Career Transition</td>
<td>Transition to Fac.</td>
</tr>
</tbody>
</table>
| K99s/R00s | Pathway to Independence Programs  
1) Parent  
2) NIAID Physician-Scientists | Transition to Fac.           |
| K08     | Mentored Clinical Scientist Research              | MDs/Clinicians               |
| K23     | Mentored Patient-Oriented Research                | MDs/Clinicians               |
| K24     | Midcareer Investigator Award                      | MDs/Clinicians               |
| K25     | Mentored Quantitative Research                    | Specific Research            |
| K01     | Mentored Research Scientist                       | Specific Research            |
# Transition Ks: K22 and K99s

**Two Phases:**

**Postdoc Phase 1** – application submission - IRG review, Council

**Faculty Phase 2** – after secure faculty position application – Admin Staff Review

<table>
<thead>
<tr>
<th>Candidate</th>
<th>Program</th>
<th>Mentor (on app)</th>
<th>Intent</th>
<th>Eligibility</th>
<th>Support</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ph.D. (and MD)</td>
<td>K22</td>
<td>NO</td>
<td>Transition from postdoc to Faculty Position</td>
<td>Up to 5 yr postdoc</td>
<td>Phase I - $0</td>
<td>Phase I – up to 1 yr</td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Phase 2 - $149K yr1 $100K yr2</td>
<td>Phase 2: 2 years</td>
</tr>
<tr>
<td>Ph.D. (and MD)</td>
<td>K99/R00s</td>
<td>YES</td>
<td>Transition from postdoc to Faculty Position</td>
<td>Up to 4 yr postdoc - non-US cit allowed</td>
<td>Phase I – $ salary</td>
<td>Phase I – up to 2 yrs</td>
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<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td>Phase 2– $249K/yr</td>
<td>Phase 2: 2 years*</td>
</tr>
</tbody>
</table>

*Other NIH ICs allow 3 years R00 support*
## K22 vs K99s at NIAID

<table>
<thead>
<tr>
<th>Comparison</th>
<th>K99s</th>
<th>K22</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open to Non-US citizens</td>
<td>⭐</td>
<td></td>
</tr>
<tr>
<td>Spend more time in Program (1 yr postdoc required)</td>
<td>⭐</td>
<td>⭐</td>
</tr>
<tr>
<td>More $ (~$500K res support)</td>
<td>⭐</td>
<td></td>
</tr>
<tr>
<td>Hypercompetitive Program (NIAID funds few/year)</td>
<td></td>
<td>⭐</td>
</tr>
<tr>
<td>Fund by K Payline and in each Council Round</td>
<td></td>
<td>⭐</td>
</tr>
<tr>
<td>NIAID Funds More of These</td>
<td></td>
<td>⭐</td>
</tr>
</tbody>
</table>
2 K99/R00 Programs at NIAID

NIH K99/R00 (Parent)  
PA-16-193

NIAID Physician Scientist (PS) K99/R00  
PAR-17-329

Independent Researcher

Able to apply for NIH R01 Awards

Both programs are open to Non-U.S. Citizens
Why Different K99/R00 Programs?

Different Goals: 1) open to all eligible, 2) open to promote PS Workforce

- Physician-Scientist Workforce Working Group (PSW-WG) 2014 report said “NIH should help sustain and strengthen a robust and diverse PSW” and they recommended a separate PS K99/R00 FOA

- NIAID targets PS K99/R00 to develop more PS in our mission areas
<table>
<thead>
<tr>
<th>NIH Parent K99/R00</th>
<th>NIAID PS K99/R00</th>
</tr>
</thead>
<tbody>
<tr>
<td>At least 1 specific aim must be clinical or translational research</td>
<td></td>
</tr>
<tr>
<td>Mini 75% effort devoted to the K99 research</td>
<td>⭐</td>
</tr>
<tr>
<td>Mini 50% effort devoted to the K99 research (rest for clinical duties)</td>
<td>⭐</td>
</tr>
</tbody>
</table>

*PS = Physician Scientist

**NIH Parent K99/R00 vs NIAID PS**

At least 1 specific aim must be clinical or translational research.

Mini 75% effort devoted to the K99 research.

Mini 50% effort devoted to the K99 research (rest for clinical duties)
## Clinical Ks: K08, K23, K24

<table>
<thead>
<tr>
<th></th>
<th>K08</th>
<th>K23</th>
<th>K24</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Eligible Individuals</strong></td>
<td>Clinical Doctoral Degree (MD, DO, DDS, DMD, OD, DC, PharmD, ND &amp; DVM. PhD in clinical area (e.g., clinical psychology)</td>
<td></td>
<td>Must have R01 award</td>
</tr>
<tr>
<td></td>
<td>US citizen, perm resident</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Postdoc training (residents, fellows), junior faculty</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>--</td>
<td>Must have R01 award</td>
<td></td>
</tr>
<tr>
<td><strong>Mentorship</strong></td>
<td>Requires a Mentor</td>
<td>Must be Mentor</td>
<td></td>
</tr>
<tr>
<td><strong>Research</strong></td>
<td>Basic and clinical</td>
<td>Clinical (POR)</td>
<td>Clinical (POR)</td>
</tr>
<tr>
<td><strong>$ Salary/Res</strong></td>
<td>Up to $100K/ $50K</td>
<td>Up to $100K/ $50K</td>
<td>Max for 50% effort/ $50K</td>
</tr>
</tbody>
</table>

**POR:** Patient Oriented Res - res w/human subjects (or material of human origin) from which investigator directly interacts w/ human subjects. Must know patient identity.
# Specific Res Ks: K01, K25

<table>
<thead>
<tr>
<th>Eligible Individuals</th>
<th>K01</th>
<th>K25</th>
</tr>
</thead>
<tbody>
<tr>
<td>US citizen, perm resident</td>
<td>Research (PhD) or Clinical (MD., etc.)</td>
<td>Postdoc, junior faculty</td>
</tr>
</tbody>
</table>

| Specific Research | At NIAID - only fields of epi, computational modeling techniques and outcomes research (research that seeks to understand the end results of particular health care practices and interventions) in infectious, immunologic and/or allergic diseases. | Applicant must have quantitative background - PhD in physics, math, engineering, chemistry, etc. and proposed biomedical research. |

| Salary and Res support | Up to $75K/yr $25K/yr | Up to $75K/yr $20K/yr |
### “R” Programs

<table>
<thead>
<tr>
<th>Code</th>
<th>Program Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>R01</td>
<td>Research Project Grant</td>
<td>Primary funding mechanism for investigator-initiated research</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Up to 5 years and $500K per year (requires prior approval for projects greater than $500K).</td>
</tr>
<tr>
<td>R03</td>
<td>Small Research Grant Project</td>
<td>Up to 2 years and $50K per year</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Not all ICs support this mechanism</td>
</tr>
<tr>
<td>R13</td>
<td>Support for Conferences and Scientific Meetings</td>
<td></td>
</tr>
<tr>
<td>R15</td>
<td>Academic Research Enhancement Award (AREA)</td>
<td>Small-scale health-related research projects at eligible domestic institutions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Up to 3 years and $300K total direct costs</td>
</tr>
<tr>
<td>R21</td>
<td>Exploratory Development Research Grant</td>
<td>Foster the introduction of novel scientific ideas, model systems, tools, agents, targets and technologies</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Break new ground or extend previous discoveries toward new directions or applications</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Up to 2 years and $275K total direct costs</td>
</tr>
<tr>
<td>R41/R42</td>
<td>Small Business Technology Transfer Grant (STTR)</td>
<td></td>
</tr>
<tr>
<td>R43/R44</td>
<td>Small Business Innovation Research Grant (SBIR)</td>
<td></td>
</tr>
</tbody>
</table>
## UCSF’s NIH Support, 2018

<table>
<thead>
<tr>
<th>Program</th>
<th>NIH-wide</th>
<th>NIAID</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$ Amount</td>
<td># Awards</td>
</tr>
<tr>
<td>RPGs</td>
<td>97,295,360</td>
<td>203</td>
</tr>
<tr>
<td>Other Res-Related</td>
<td>11,244,769</td>
<td>40</td>
</tr>
<tr>
<td>Individual Training</td>
<td>1,705,430</td>
<td>35</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>110,245,559</strong></td>
<td><strong>278</strong></td>
</tr>
</tbody>
</table>

Part I

Questions?
Part II

Grantwriting: How to Apply for Funding
Grantsmanship
THE ART OF PERSUASION

Your job is to PERSUADE reviewers of significance of the problem you are proposing that MUST be addressed. And that in your hands (prelim data), in your environment and with your team (mentor, etc.) you can add new knowledge to your field.
We Know the Stats…

- 1973 > half PhDs in bio sciences got tenure-track faculty within six years
- Today only 15%
- Producing more PhDs than Faculty Positions
- Hypercompetitive Funding Climate
A Response:

- NIH Promoting Other Career Outcomes (e.g., BEST)

- For those who want research career as a PI - **Persistence** is key.
Applicant & Mentor Initiate Research Idea

Mentor’s Institution Submits Application

Electronic Submission

National Institutes of Health

Assign to Institute and Study Panel

Study Panel

NIH Institutes (24 with funding authority)

Leaders in the biological and medical sciences, education, health care, and public affairs.

Advisory Council

Evaluate Relevance

Recommended Action

Take Action

Allocation of Funds

Institute Director

NIH Funding Cycle

Start Here

End Here

Summary Statement of Initial Review

Review of Scientific Merit

NOT FUNDED? RESUBMIT
Grantwriting: *How to Apply*

READ all relevant information:

1. Funding Opportunity Announcement (FOA)
2. Notices
3. SF424 Application Instructions
4. Supplemental App Instructions
5. NIH and NIAID Websites

*Before you WRITE you must to READ!*
Funding Opportunity Announcement (FOA)

Special Note: Not all NIH Institutes and Centers participate in Parent Announcements. Applicants should carefully note which ICs participate in this announcement at the Table of IC-Specific Information, Requirements and Staff Contacts website. ICs that do not participate in this announcement will not be strongly encouraged.

Funding Opportunity Title
NIH Pathway to Independence Award (Parent K99/R00)

Activity Code
K99/R00 Career Transition Award/Research Transition Award

Announcement Type
Reissue of PA-16-077

Related Notices
- June 21, 2016 - Modification of No-Cost Extension and Carryover of Funds Policies for the NIH Pathway to Independence Award. See Notice NOT-1
- June 2, 2016 - Notice to Extend the Expiration Date for PA-16-193. See Notice NOT-OD-16-102.

Funding Opportunity Announcement (FOA) Number
PA-16-193

Companion Funding Opportunity
SF424 Application Instructions

U.S. Department of Health and Human Services
Public Health Service

SF424 (R&R) Application
Guide for NIH and Other
PHS agencies

A guide developed and maintained by NIH for preparing and submitting applications via Grants.gov to NIH and Other PHS agencies using the SF424 (R&R)*
Supplemental Instructions

CAREER DEVELOPMENT INSTRUCTIONS
FOR NIH AND OTHER PHS AGENCIES

SF424 (R&R) APPLICATION PACKAGES

Guidance developed and maintained by NIH for preparing and submitting applications via Grants.gov to NIH and other PHS
NIH Website


How to Apply - Application Guide

Use the application instructions found on this page along with the guidance in the funding opportunity announcement to submit grant applications to NIH, the Centers for Disease Control and Prevention, the Food and Drug Administration, and the Agency for Healthcare Research and Quality.

Prepare to Apply
- Systems and Roles
- Register
- Understand Funding Opportunities
- Types of Applications
- Submission Options
- Obtain Software

Write Application
- Write Your Application
- Develop Your Budget
- Format Attachments
- Rules for Text Fields
- Page Limits
- Data Tables
- Reference Letters
- Biosketches

Submit
- Submit, Track, and View
- How We Check for Completeness
- Changed/Corrected Applications

Important:
Access forms through the funding opportunity announcement.
NIAID Website
https://www.niaid.nih.gov/grants-contracts/apply-grant

Apply for a Grant

Sample Applications and More
Some useful samples and examples that are part of the grant application from NIAID and NIH, including sample applications and summary statements, data sharing, and model organism sharing plans.

Determine Eligibility for NIAID Grants
Before you contemplate applying for funding, see if and how you may fit in at NIH by assessing whether your area of science falls within the NIH mission. You can also learn about qualifying for an independent grant, view options at earlier career stages, get the scoop on the NIH “new investigator” status, and see how to qualify as an investigator or organization working outside the United States.

Preparing Your Application
Writing a successful grant application requires careful planning, starting with choosing a project that will excite the application’s audience, its peer reviewers. In this
AFTER Thoroughly Reading Materials

Contact person(s) listed on FOA under **TABLE IC-Specific Staff Contacts**

<table>
<thead>
<tr>
<th>HOME</th>
<th>ABOUT GRANTS</th>
<th>FUNDING</th>
<th>POLICY &amp; COMPLIANCE</th>
<th>NEWS &amp; EVENTS</th>
<th>ABOUT OER</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Institute of Allergy and Infectious Diseases (NIAID)</td>
<td>NIAID Specific Information:</td>
<td>Eligible candidates must have a clinical doctoral degree, current work in biomedical research, including translational research, and a professional license to practice in the United States.</td>
<td>See <a href="https://www.niaid.nih.gov/grants-contracts/career-development-awards">https://www.niaid.nih.gov/grants-contracts/career-development-awards</a> for information about NIAID Career Development Awards.</td>
<td></td>
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<tr>
<td><strong>Scientific Program Contact:</strong></td>
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<tr>
<td>Shawn Gaillard, Ph.D.</td>
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<tr>
<td>Phone: 240-627-3857</td>
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<tr>
<td>Email: <a href="mailto:Shawn.Gaillard@nih.gov">Shawn.Gaillard@nih.gov</a></td>
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<tr>
<td><strong>Grants Management Contact:</strong></td>
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<td>Mable Nee</td>
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<tr>
<td>Phone: (301) 761-7593</td>
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<tr>
<td>Email: <a href="mailto:Mable.Nee@nih.gov">Mable.Nee@nih.gov</a></td>
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</table>
Contact Scientific Staff

- Scientific Contact (Name, Phone and Email)
- Do NOT “Cold Call!”
- Send an **EMAIL** to request setting up a time to talk
  - Email include:
    - Name of program(s) of interest
    - Your NIH-formatted Biosketch eligible?
    - Specific Aims Page align with NIH IC mission?
    - General questions you may have
    - Several dates/times available
Prepare to Write a Grant Application

Critically Assess Yourself
- Do you have the necessary expertise, resources, personnel and prelim data to be competitive?

Assess Potential for Your Idea
- What has already been done, reported and funded in your field?
- What are the “gaps”?
- How can you take your field a step farther?

Assess the Competition
- Who are the important “players” in field?
- What have they accomplished?
- Search NIH Reporter database of funded grants

Remember they might be your reviewers?
NIH RePORTER

Search NIH funded projects

- Over 200 disease categories
- Keywords
- Investigator
- Organization
- Funding Mechanism
- Study Section
- Institute or Center (IC)

Recent Awards
There is no amount of Grantsmanship that will turn a bad idea into a good one...

But there are many ways to disguise a good idea!

Dr. William Raub
Past Deputy Director, NIH
Write, Edit and Proof like a Pro

- Start with an outline
- Write a topic sentence for each main point
- Make only one point in each paragraph, stating it clearly
- KISS: Keep It Short - keep paragraphs short, starting with basic ideas and progress to complex ones
- Use short sentences with basic structure - subject, verb & object agreement. Break-up long sentences.
- Use transitions to start new paragraph, topic - "Additionally," "Furthermore," "In contrast," etc.
- Keep related ideas & information close together
- Use strong action words – "We will develop a cell line" not "A cell line will be developed"

If Writing Is Not Your Forte, Get Help!
Writing Your Application

Address the **Review Criteria** (FOA) in your application = what reviewers will use to access the merits of your Application! Your “Cheat Sheet!”

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- Part 1. Overview Information
- Part 2. Full Text of the Announcement

- Section I. Funding Opportunity Description
- Section II. Award Information
- Section III. Eligibility Information
- Section IV. Application and Submission Information
- Section V. Application Review Information
- Section VI. Award Administration Information
- Section VII. Agency Contacts
- Section VIII. Other Information
Section V. Application Review Information
1. Criteria

Only the review criteria described will be considered in the review process.

Ask Yourself the Review Criteria Questions and Address them in your Application:
“K” Review Criteria

1. Candidate
2. Career Development Plan/Career Goals
3. Research Plan
4. Mentor (K01,08,23,25,99s), Collaborators, Consultants (+K22,K24)
5. Environment & Institutional Commitment
Candidate

- Does the candidate have the potential to develop as an independent and productive researcher?
- Are the candidate's prior training and research experience appropriate for this award?
- Is the candidate's academic, clinical (if relevant), and research record of high quality?
- Is there evidence of the candidate's commitment to meeting the program objectives to become an independent investigator in research?
- Do the letters of reference address the above review criteria, and do they provide evidence that the candidate has a high potential for becoming an independent investigator?

Career Development Plan/Career Goals and Objectives

- What is the likelihood that the plan will contribute substantially to the scientific development of the candidate and lead to scientific independence?
- Are the candidate's prior training and research experience appropriate for this award?
- Are the content, scope, phasing, and duration of the career development plan appropriate when considered in the context of prior training/research experience and the stated training and research objectives for achieving research independence?
- Are there adequate plans for monitoring and evaluating the candidate's research and career development progress?
- If proposed, will the clinical trial experience contribute to the applicant's research career development?
Research Plan

- Are the proposed research questions, design, and methodology of significant scientific and technical merit?
- Is there a strong scientific premise for the project?
- Has the candidate presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?
- Has the candidate presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?
- Is the research plan relevant to the candidate's research career objectives?
- Is the research plan appropriate to the candidate's stage of research development and as a vehicle for developing the research skills described in the career development plan?
- If proposed, will the clinical trial experience contribute to the proposed research project?

Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)

- Are the qualifications of the mentor(s) in the area of the proposed research appropriate?
- Does the mentor(s) adequately address the candidate's potential and his/her strengths and areas needing improvement?
- Is there adequate description of the quality and extent of the mentor's proposed role in providing guidance and advice to the candidate?
- Is the mentor's description of the elements of the research career development activities, including formal coursework adequate?
- Is there evidence of the mentor's, consultant's, and/or collaborator's previous experience in fostering the development of independent investigators?
- Is there evidence of the mentor's current research productivity and peer-reviewed support?
- Is active/pending support for the proposed research project appropriate and adequate?
- Are there adequate plans for monitoring and evaluating the career development awardee's progress toward independence?
- If the applicant is proposing to gain experience in a clinical trial as part of his or her research career development, is there evidence of the appropriate expertise, experience, and ability on the part of the mentor(s) to guide the applicant during participation in the clinical trial?
Environment & Institutional Commitment to the Candidate

- Is there clear commitment of the sponsoring institution to ensure that the required minimum of the candidate's effort will be devoted directly to the research described in the application, with the remaining percent effort being devoted to an appropriate balance of research, teaching, administrative, and clinical responsibilities?
- Is the institutional commitment to the career development of the candidate appropriately strong?
- Are the research facilities, resources and training opportunities, including faculty capable of productive collaboration with the candidate adequate and appropriate?
- Is the environment for scientific and professional development of the candidate of high quality?
- Is there assurance that the institution intends the candidate to be an integral part of its research program as an independent investigator?
What Makes a Research Project Outstanding?

- Addresses important problem clearly
- Potential to lead to seminal new observations
- Lays foundation for further research in field
- Addresses difficult problem in a way that seems simple in retrospect

*Makes reviewers wonder why they didn’t think of the idea before!*
Key Features of Successful Applications

Hypothesis
- Meaningful hypothesis AND means of testing it
- Sound rationale for hypothesis

Preliminary Data
- Documents feasibility
- Shows ability to interpret results
- Include alternative interpretations/address limitations

Well Organized Research Plan
- Aims focused (related to each other and hypothesis)
- Rationale for methods proposed, with alternatives
- Research flow and priorities clear
- Sufficient experimental detail to show you understand methods
Review Process

- At NIAID Ks reviewed in our Chartered Committees based on science:
  - Acquired Immunodeficiency Syndrome Research Review Committee (AIDS)
  - Allergy, Immunology, and Transplantation Research Committee (AITC)
  - Microbiology and Infectious Diseases Research Committee (MID)
  - Microbiology and Infectious Diseases B Subcommittee (MID B)

- Scientific Review Officer (SRO) assigns K applications to review panel members (~ 20 or so scientific experts). 3 reviewers assigned to each application.

- Reviewers are:
  - overly committed, inherently skeptical and “informed strangers”

- Make their job easier:
  - well organized, clearly written. Guide them w/labeled graphics

- Avoid things that irate:
  - typos, font too small, mislabeled graphics, mathematical errors
Review Process

- Reviewers read assigned applications on their own time.

- Use Review Criteria to assess merits of applications, scores each application from “1 – 9”.

Application by Application Discussion:
- Reviewers with conflicts of interest excused from the room.
- Assigned reviewers give their preliminary scores.
- Discussion of applicant’s scientific and technical merit.
- Other panel members join the discussion.
- Assigned reviewers give their final scores (1-9).
- All panel members (except those in conflict) give their scores, privately.
- Budget (# years) discussed, not part of the score.

MOCK STUDY SECTION YOUTUBE VIDEO
https://www.youtube.com/watch?v=lzBhKeR6VIE
Scores

Based on the 5 Review Criteria (additional Review Criteria rated as acceptable/unacceptable: Animal Welfare, Human Subjects Protections, Biohazards, Resubmission (A1))

<table>
<thead>
<tr>
<th>Overall Impact or Criterion Strength</th>
<th>Score</th>
<th>Descriptor</th>
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<tbody>
<tr>
<td>High</td>
<td>1</td>
<td>Exceptional</td>
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<tr>
<td></td>
<td>2</td>
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<td>Excellent</td>
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<td>Medium</td>
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<td>Very Good</td>
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<td></td>
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<td>8</td>
<td>Marginal</td>
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<tr>
<td></td>
<td>9</td>
<td>Poor</td>
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Additional Review Considerations (Does not affect impact score):
Authentication of Key Resources, Training in the Responsible Conduct of Research, Budget, Select Agents, Resource Sharing
So You’re Not Funded…

Most Common Reasons for Unscored or Not Recommended for Further Considerations

- 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
Regroup and Resubmit

Remember – Persistence is Key

NIH allows for original and up to one resubmission, that addresses the reviewers critiques.

Before a resubmission can be done, the applicant must have received Summary Statement (SS) from original review.

Email Program Officer indicated top of SS to set-up time to discuss your application and any next steps.
Summary Statement (Example)

Principal Investigator

Your Name, MD, PhD

Applicant Organization: Name of Your Institution

Review Group: MID-B Microbiology and Infectious Diseases B Subcommittee

Meeting Date: 02/03/2014 Council: MAY 2014 Requested Start: 07/01/2014

RFA/PA: PAR12-156

Project Title: Title of Your Proposal

SRG Action: Impact Score: 25


Human Subjects: 10-No human subjects involved

Animal Subjects: 30-Vertebrate animals involved - no SRG concerns noted

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<tr>
<th>Year</th>
<th>Direct Costs Requested</th>
<th>Estimated Total Cost</th>
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<tr>
<td>1</td>
<td>150,000</td>
<td>162,000</td>
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<tr>
<td>2</td>
<td>100,000</td>
<td>108,000</td>
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<td>TOTAL</td>
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<td><strong>Application Number</strong></td>
<td><strong>K08 AI063815-01A1</strong></td>
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<table>
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<tr>
<th><strong>Application Type</strong></th>
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<tbody>
<tr>
<td>1 - New</td>
<td>- Sequential numbering of applications submitted to particular Institute</td>
</tr>
<tr>
<td>2 - Competing Continuation</td>
<td></td>
</tr>
<tr>
<td>5 - Noncompeting Continuation</td>
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</table>

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<tr>
<th><strong>Mechanism</strong></th>
<th><strong>Support Year</strong></th>
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</thead>
<tbody>
<tr>
<td>R01, R03, R15, K01, F32, etc . . .</td>
<td>- All new applications start at -01</td>
</tr>
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<tr>
<th><strong>Institute</strong></th>
<th><strong>Suffix</strong> - <em>additional identifier</em></th>
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</thead>
<tbody>
<tr>
<td>GM (NIGMS), CA (NCI), etc . . .</td>
<td>- A1 - amended application</td>
</tr>
<tr>
<td></td>
<td>- S1 - supplement</td>
</tr>
</tbody>
</table>
Applicant & Mentor Initiate Research Idea

Electronic Submission

Mentor’s Institution Submits Application

National Institutes of Health

Assign to Institute and Study Panel

Study Panel

NIH Institutes
(24 with funding authority)

Allocation of Funds

Start Here

Conduct Research READ FOAs, etc.

Institute Director

Leaders in the biological and medical sciences, education, health care, and public affairs. Advisory Council

Evaluate Relevance

Recommended Action

Take Action

Summary Statement of Initial Review

NIH FUNDING CYCLE

Funded; Now What?
You’ll Receive a Notice of Award (NoA)

- Legally binding document
  - Award and fiscal information
  - Terms and conditions

- Grantee accepts terms and conditions of award when draws down funds
NIH Grants Policy Statement

- Is a term and condition of all NIH grant awards
- Explicitly defines roles & responsibilities

Post Award Management

- Annual Progress Report (PO reads, critiques)
- Annual Federal Financial reporting (your school BO)
- Yearly audits (as applicable)
- Closeout reporting (when required)
- Track your Application/NoA in eRA Commons
Q: **What are the most important things reviewers look for in an application?**
A: Review Criteria - Addressed Well

Q: **How connected/interdependent should your specific aims be?**
A: Aims focused (related to each other and hypothesis)

Q: **What resources are there to learn the best grant writing techniques when English is not my first language?**
A: Writing (and/or English) not your forte, get help. Numerous books.
“The Grant Application Writer’s Workbook” available at GrantCentral.com

“Writing the NIH Grant Proposal: A Step-by-Step Guide” by William Gerin

“Grant Application Writers Handbook” (4th Ed) by Liane Reif-Lehrer

“Guide to Effective Grant Writing: How to Write a Successful NIH Grant Application” by Otto O. Yang

“How to Succeed in Academics” by Edward R. B. McCabe and Linda McCabe
Earlier Questions

Q: How much preliminary data should I have in my grant proposal?
A: Enough for “Proof of Concept” reviewers can know what proposing to address aligns with prelim (and demonstrates ability)

Your Research to Fill this Knowledge Gap;
Prelim Data is Early “Proof of Concept”
Earlier Questions

Q: Do you have any K99-specific tips including how to choose which institute to target?
A: Yes, NIAID hypercompetitive – fund only a handful/year and offer less support (up to 4 years max, not 5 years as other ICs) may want to go to another IC

Q: As international postdoc…which grants are open to non-US citizens?
A: Of the Ks: Only the K99/R00s open to non-US (taxpayer funds NIH, therefore Congress wants US training focus). “R”s open to all

Q: Restrictions on type of research that can be conducted (i.e. no clinical trials)
A: Yes, At NIAID, all K applicants, except PS K99/R00, cannot propose an independent clinical trial as the lead PI. Can do CT research, just under mentor’s guidance and where mentor is lead CT PI.
Additional Questions?

Shawn Drew Gaillard, Ph.D.
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