"Words of Wisdom from a NIH Research Training Officer"

Discussion at UCSF of Research Training Programs and Grantsmanship

Shawn Gaillard, Ph.D.

March, 2018

NIAID

Agenda

Part I:

- Overview of NIH
- Research Training Programs

Part II:

- Grantwriting:

  How to Apply for Funding

NIAID

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)

Intramural:

We do research;
~1K PIs on campus

Extramural:

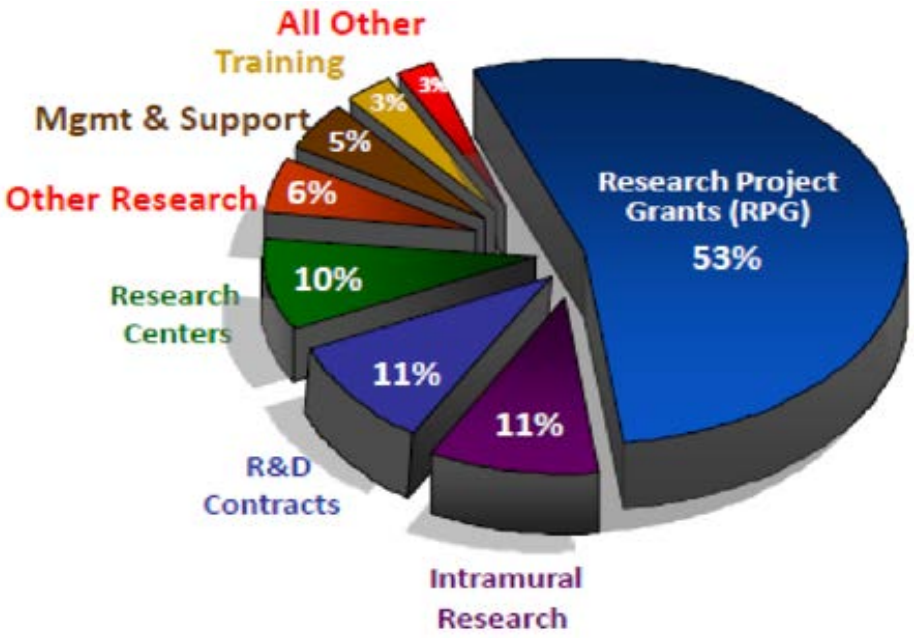
We support res;
~300K Researchers,
2.5K univ, med, other

NIAID

Mission: Improving Human Health

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.

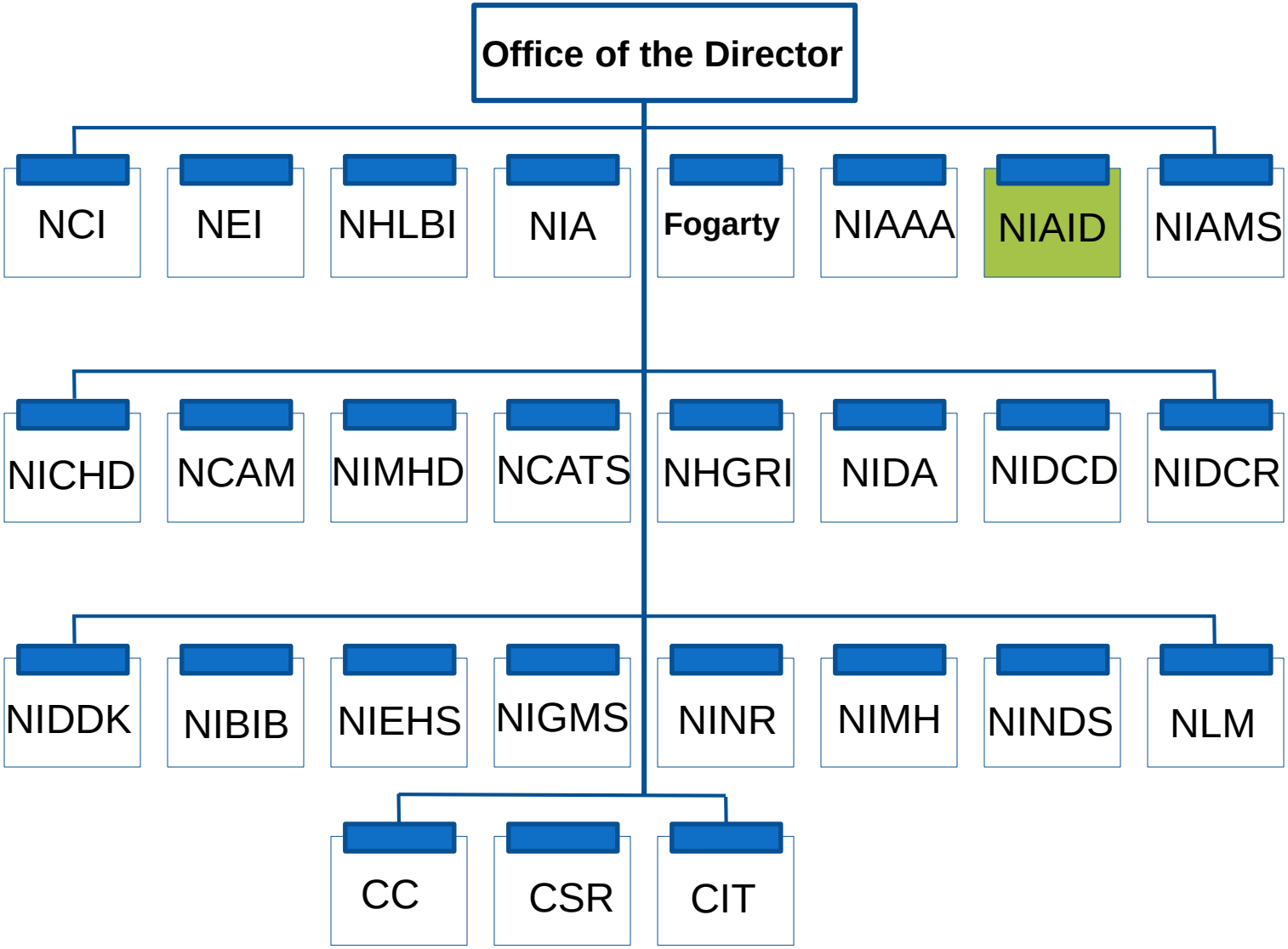
Annual Budget >$30 Billion



NIAID

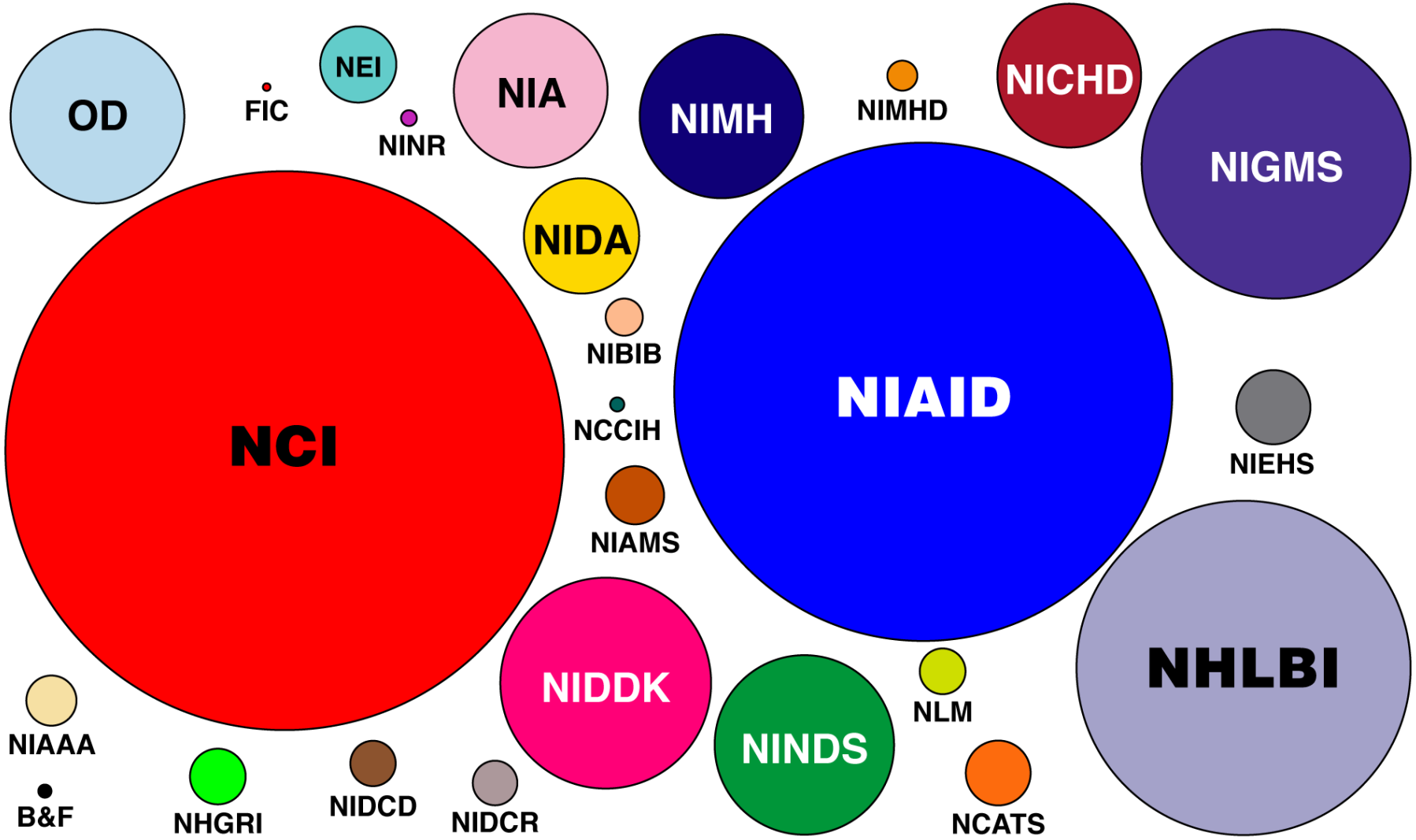
NATIONAL INSTITUTES OF HEALTH

27 Institutes and Centers



NIAID

National Institutes of Health



FY 2017 Enacted Budget for 8 Largest NIH Institutes

NCI	$5.7B
NIAID	$4.9B
NHLBI	$3.2B
NIGMS	$2.6B
NIDDK	$2.0B
NIA	$2.0B
NINDS	$1.8B
NIMH	$1.6B

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

NIAID Mission – “Maintain”

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

Source: JL Marcus et al., JAIDS, 2016

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

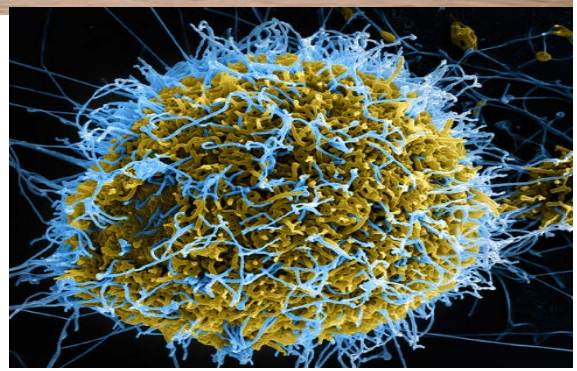
Respond rapidly to Emerging and re-emerging disease threats

New/Improved Interventions

NIAID

NIAID Mission – “Respond”

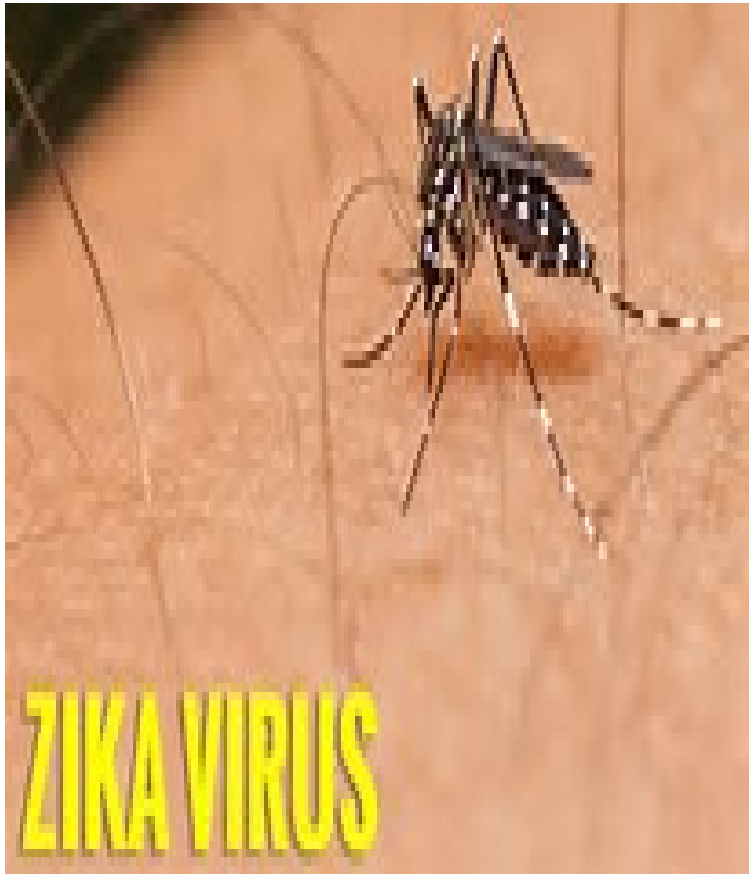
Ebola



NIAID

NIAID Mission – “Respond”

Mosquito-Borne Zika Virus



Baby Born w/Microcephaly

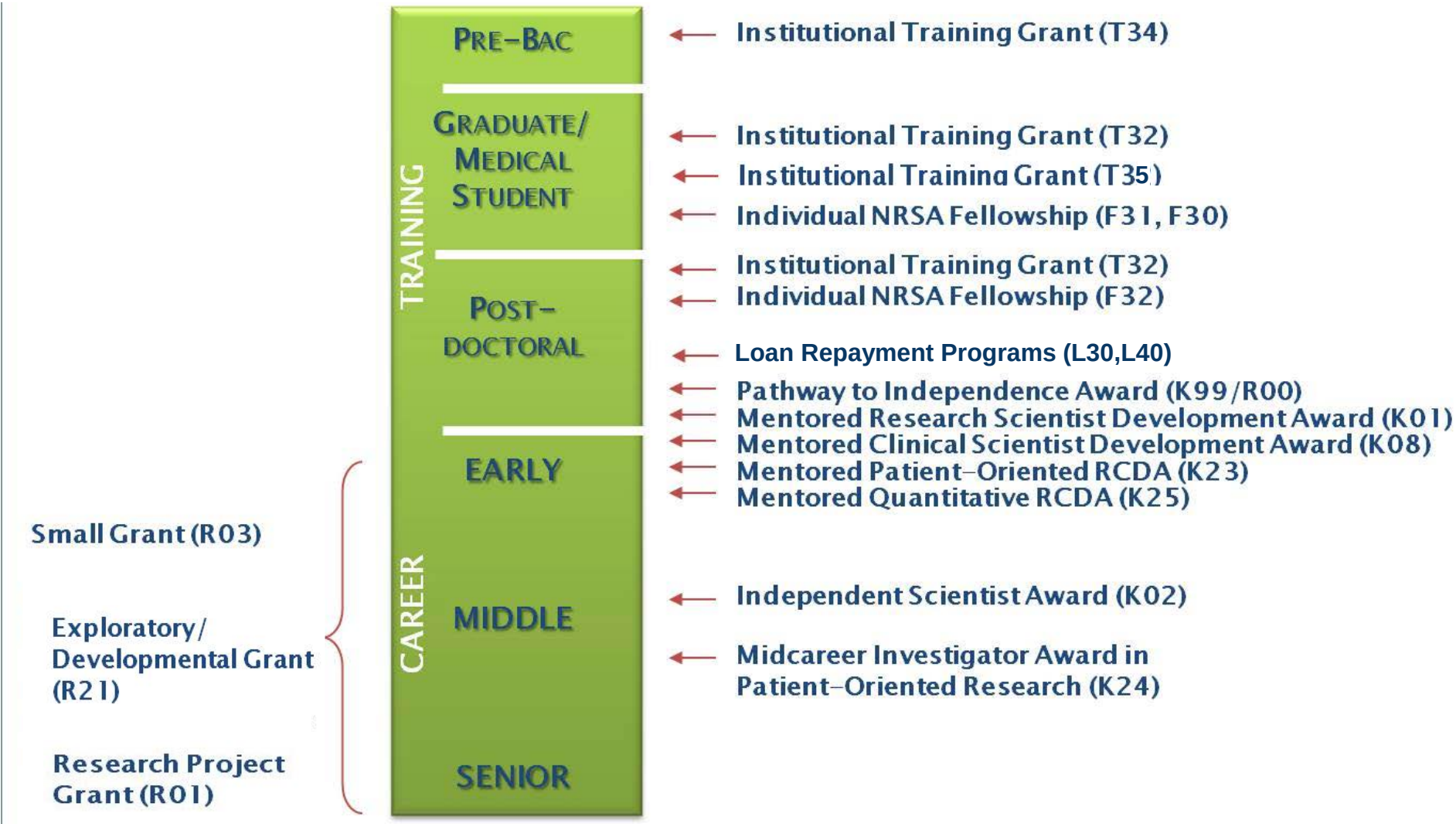
NIAID

Research Training and Career Development at NIH

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**

NIAID

Career Stages for NIH Funding



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)

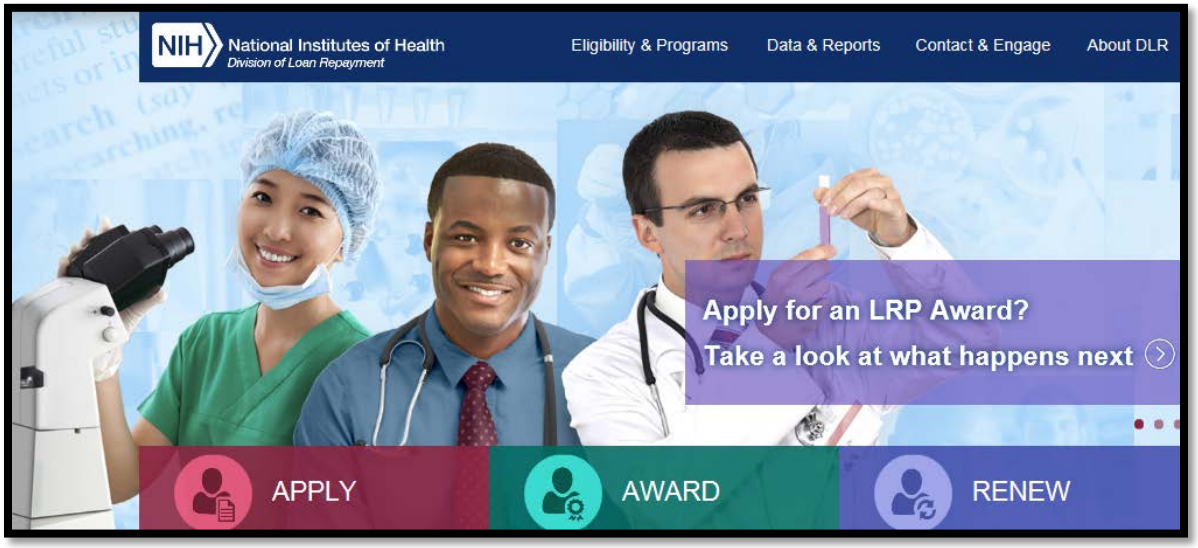
- Institutional (apply at your school) "T" – Training:
  - T35 (short-term)
  - T32 – Predoctoral and Postdoctoral

NIAID

Loan Repayment Programs

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

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



NIAID

Research Career "K" Development

https://researchtraining.nih.gov/programs/career-development

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

GOAL:

Foster Research Independence (e.g., R01)

NIAID

NIH "K" Evaluation

http://grants.nih.gov/training/K_Awards_Evaluation_FinalReport_20110901.pdf

- 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!

NIAID

https://researchtraining.nih.gov/programs/career-development

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

* Open to non-US citizens

NIAID Ks

https://www.niaid.nih.gov/grants-contracts/career-development-awards

K	Program Name	Category
K22	Career Transition	**Transition to Fac.**
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**

NIAID

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

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

** Other NIH ICs allow 3 years R00 support*

K22 vs K99s at NIAID

	K99s	K22
Open to Non-US citizens	★	
Spend more time in Program (1 yr postdoc required)	★	
More $ (~$500K res support)	★	
Hypercompetitive Program (NIAID funds few/year)	★	
Fund by K Payline and in each Council Round		★
NIAID Funds More of These		★

NIAID

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

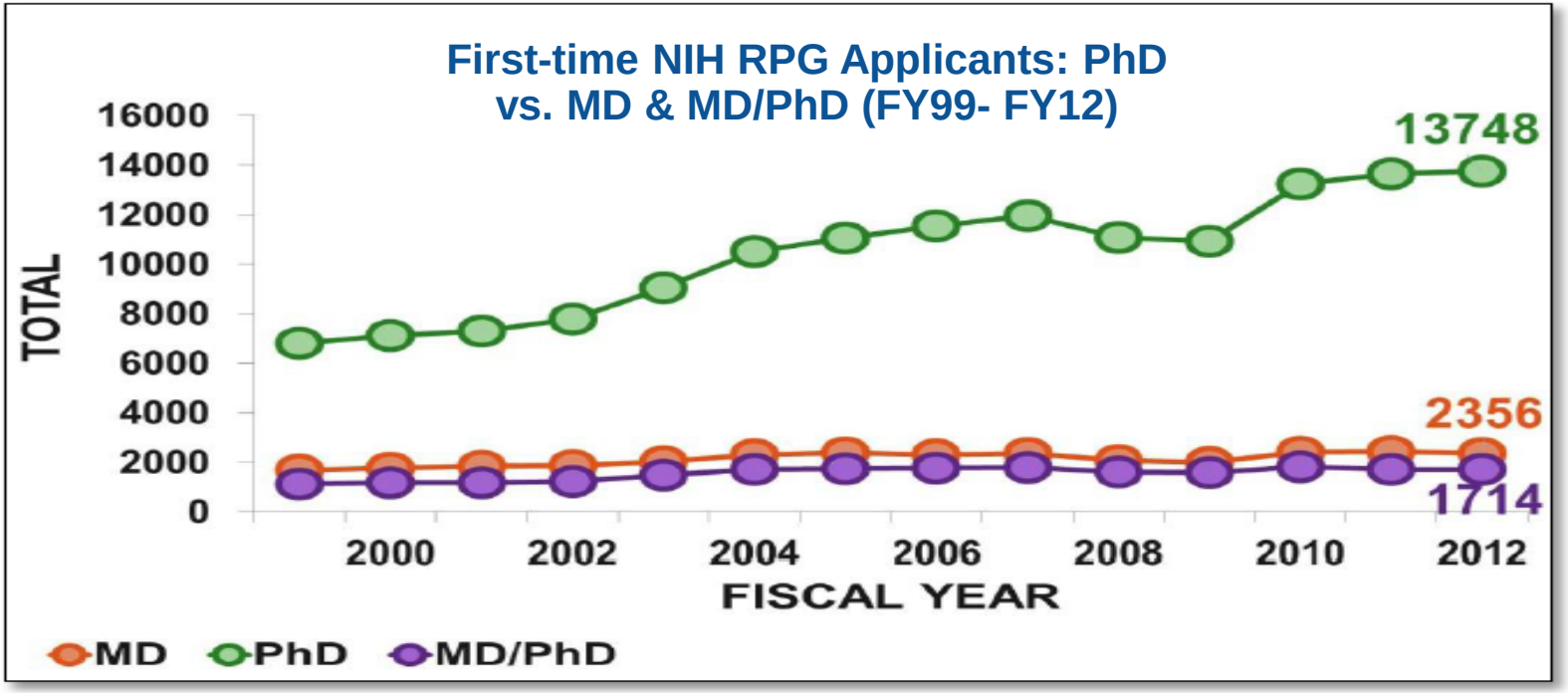
NIAID

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



NIAID

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

**PS = Physician Scientist*

	NIH Parent K99/R00	NIAID PS K99/R00
At least 1 specific aim must be clinical or translational res		★
Mini 75% effort devoted to the K99 research	★	
Mini 50% effort devoted to the K99 research (rest for clinical duties)		★

NIAID

Clinical Ks: K08, K23, K24

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

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

	K01	K25
Eligible Individuals	US citizen, perm resident	
	Research (PhD) or Clinical (MD., etc.)	
	Postdoc, junior faculty	
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

NIAID

"R" Programs

R01 Research Project Grant

- *Primary funding mechanism for investigator-initiated research*
- *Up to 5 years and $500K per year (requires prior approval for projects greater than $500K).*

R03 Small Research Grant Project

- *Up to 2 years and $50K per year*
- *Not all ICs support this mechanism*

R13 Support for Conferences and Scientific Meetings

R15 Academic Research Enhancement Award (AREA)

- *Small-scale health-related research projects at eligible domestic institutions*
- *Up to 3 years and $300K total direct costs*

R21 Exploratory Development Research Grant

- *Foster the introduction of novel scientific ideas, model systems, tools, agents, targets and technologies*
- *Break new ground or extend previous discoveries toward new directions or applications*
- *Up to 2 years and $275K total direct costs*

R41/R42 Small Business Technology Transfer Grant (STTR)

R43/R44 Small Business Innovation Research Grant (SBIR)

NIAID

UCSF's NIH Support, 2018

	NIH-wide		NIAID	
Program	**$ Amount**	**# Awards**	**$ Amount**	**# Awards**
RPGs	97,295,360	203	23,129,383	38
Other Res-Related	11,244,769	40	1.024,729	6
Individual Training	1,705,430	35	257,713	5
Total	**110,245,559**	278	**24,411,825**	49

https://report.nih.gov/index.aspx

NIAID

Part I

Questions?

Part II

Grantwriting: How to Apply for Funding

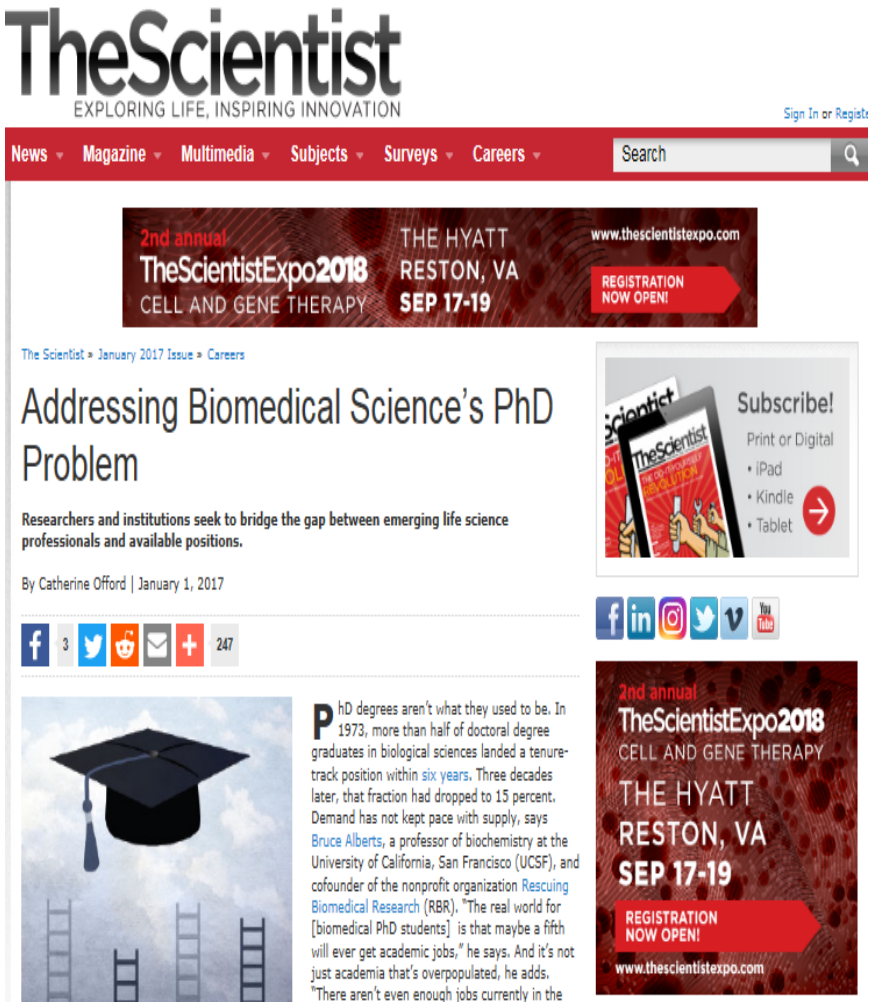
Grantsmanship

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



TheScientist
EXPLORING LIFE, INSPIRING INNOVATION

Sign In or Registe

News Magazine Multimedia Subjects Surveys Careers Search

2nd annual TheScientistExpo2018 CELL AND GENE THERAPY THE HYATT RESTON, VA SEP 17-19 www.thescientistexpo.com REGISTRATION NOW OPEN!

The Scientist » January 2017 Issue » Careers

Addressing Biomedical Science's PhD Problem

Researchers and institutions seek to bridge the gap between emerging life science professionals and available positions.

By Catherine Offord | January 1, 2017

3 247

PhD degrees aren't what they used to be. In 1973, more than half of doctoral degree graduates in biological sciences landed a tenure-track position within six years. Three decades later, that fraction had dropped to 15 percent. Demand has not kept pace with supply, says Bruce Alberts, a professor of biochemistry at the University of California, San Francisco (UCSF), and cofounder of the nonprofit organization Rescuing Biomedical Research (RBR). "The real world for [biomedical PhD students] is that maybe a fifth will ever get academic jobs," he says. And it's not just academia that's overpopulated, he adds. "There aren't even enough jobs currently in the

Subscribe! Print or Digital • iPad • Kindle • Tablet

2nd annual TheScientistExpo2018 CELL AND GENE THERAPY THE HYATT RESTON, VA SEP 17-19 REGISTRATION NOW OPEN! www.thescientistexpo.com

The Scientist, January 2017 Issue, Careers

We Know the Stats…

A Response:

- NIH Promoting Other Career Outcomes (e.g., BEST)
- For those who want research career as a PI - ***Persistence*** is key.

TheScientist
EXPLORING LIFE, INSPIRING INNOVATION

Sign In or Regist

News Magazine Multimedia Subjects Surveys Careers Search

2nd annual TheScientistExpo2018 CELL AND GENE THERAPY THE HYATT RESTON, VA SEP 17-19 www.thescientistexpo.com REGISTRATION NOW OPEN!

The Scientist » January 2017 Issue » Careers

Addressing Biomedical Science's PhD Problem

Researchers and institutions seek to bridge the gap between emerging life science professionals and available positions.

By Catherine Offord | January 1, 2017

3 247

PhD degrees aren't what they used to be. In 1973, more than half of doctoral degree graduates in biological sciences landed a tenure-track position within six years. Three decades later, that fraction had dropped to 15 percent. Demand has not kept pace with supply, says Bruce Alberts, a professor of biochemistry at the University of California, San Francisco (UCSF), and cofounder of the nonprofit organization Rescuing Biomedical Research (RBR). "The real world for [biomedical PhD students] is that maybe a fifth will ever get academic jobs," he says. And it's not just academia that's overpopulated, he adds. "There aren't even enough jobs currently in the

Subscribe! Print or Digital • iPad • Kindle • Tablet

2nd annual TheScientistExpo2018 CELL AND GENE THERAPY THE HYATT RESTON, VA SEP 17-19 REGISTRATION NOW OPEN! www.thescientistexpo.com

The Scientist, January 2017 Issue, Careers

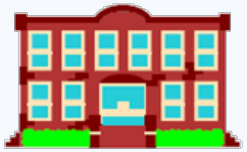
NIH FUNDING CYCLE

Start Here

Applicant & Mentor Initiate Research Idea

Conduct Research
READ FOAs, etc.

Mentor's Institution Submits Application



Electronic Submission

National Institutes of Health

NIH

Assign to Institute and Study Panel

center for scientific review

Study Panel

Review of Scientific Merit

NIH Institutes
(24 with funding authority)

NCI	NIAMS	NIEHS	FIC
NEI	NIBIB	NIGMS	NCATS
NHLBI	NICHD	NIMH	NCCAM
NHGRI	NIDCD	NIMHD	NIAID
NIA	NIDCR	NINDS	NIDA
NIAA	NIDDK	NINR	NIAID

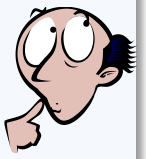
Summary Statement of Initial Review

Evaluate Relevance

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

Advisory Council

Recommend Action



Institute Director

Take Action

Allocation of Funds

End Here

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

Links on FOA

Before you WRITE you must to READ!

NIAID

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 annou
requirements at the Table of IC-Specific Information, Requirements and Staff Contacts website. ICs that do not participate in this announcement will not c
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-
- 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

FORMS VERSION E SERIES
Released: September 25, 2017
Revised: December 29, 2017

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

https://grants.nih.gov/grants/how-to-apply-application-guide.html

National Institutes of Health
Office of Extramural Research

Grants & Funding
NIH's Central Resource for Grants and Funding Information

Entire Site | Search this Site

eRA | NIH Staff | Glossary & Acronyms | FAQs | Help

HOME | ABOUT GRANTS | FUNDING | POLICY & COMPLIANCE | NEWS & EVENTS | ABOUT OER

Home » About Grants » How to Apply - Application Guide

How to Apply - Application Guide

Important:
Access forms through the funding opportunity announcement.

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

NIAID Website

https://www.niaid.nih.gov/grants-contracts/apply-grant

National Institute of Allergy and Infectious Diseases

Search NIAID

Search

RESEARCH | DISEASES & CONDITIONS | GRANTS & CONTRACTS | CLINICAL TRIALS | NEWS & EVENTS | ABOUT NIAID

Share This:

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.

- New Investigators
- International Applications
- Training & Career Development
- Identifying Collaboration Opportunities

Preparing Your Application ›

Writing a successful grant application requires careful planning, starting with choosing a project that will excite the applicatio's audience, its peer reviewers. In this

- Draft Specific Aims
- Outline Your Experiments
- Know Your Audience

AFTER Thoroughly Reading Materials

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

HOME | ABOUT GRANTS | FUNDING | POLICY & COMPLIANCE | NEWS & EVENTS | ABOUT OER

National Institute of Allergy and Infectious Diseases (NIAID)

Scientific Program Contact:
Shawn Gaillard, Ph.D.
Phone: 240-627-3857
Email: Shawn.Gaillard@nih.gov

Grants Management Contact:
Mable Nee
Phone: (301) 761-7593
Email: Mable.Nee@nih.gov

NIAID Specific Information:

Eligible candidates must have a clinical doctoral degree, current work in biom
research, including translational research, and a professional license to practi
States.

See https://www.niaid.nih.gov/grants-contracts/career-development-awards f
NIAID Career Development Awards.

Salary Support: Up to $100,000 plus fringe benefits per year.
Research Support: Up to $50,000 per year.

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?

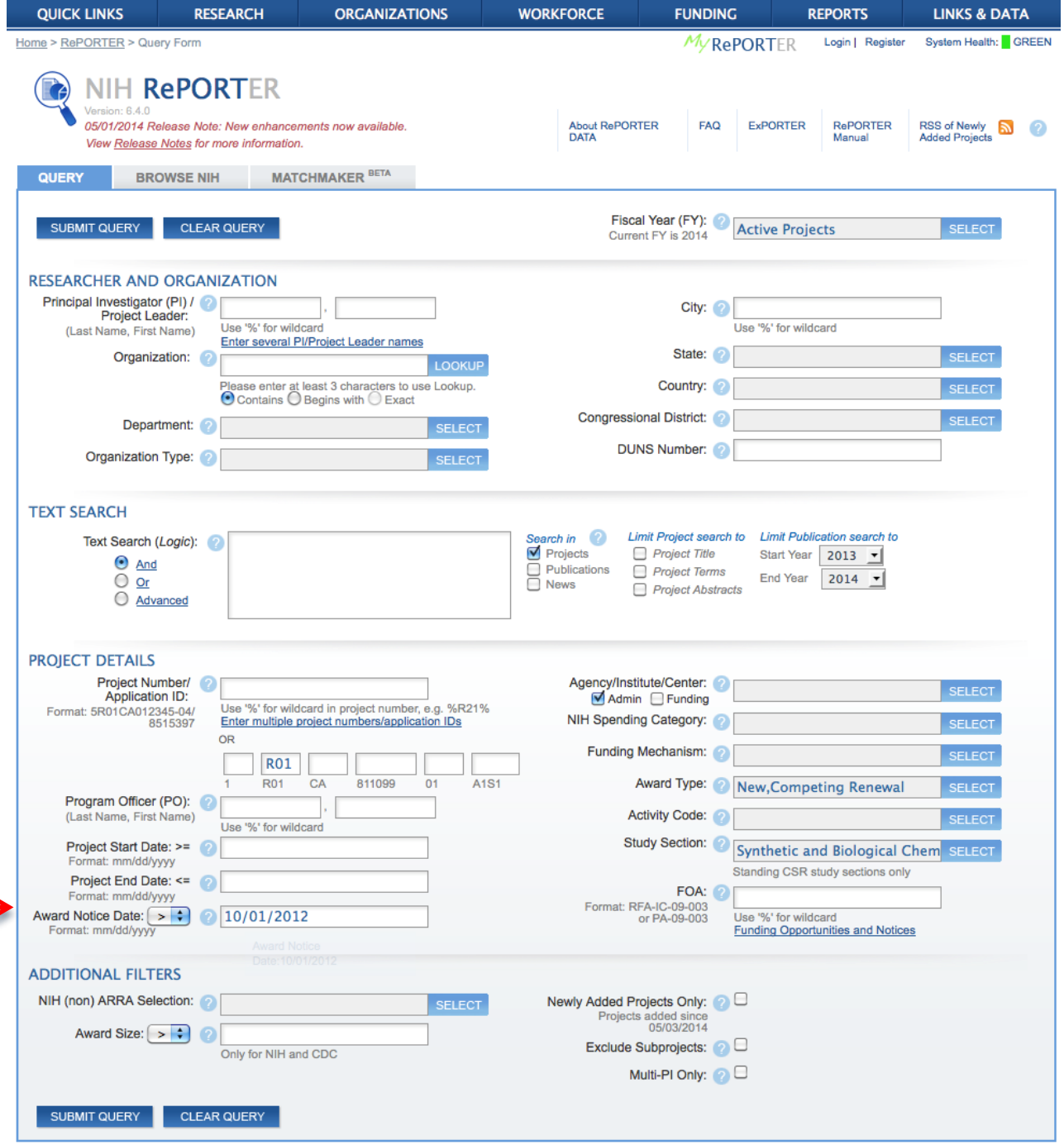
NIAID

NIH RePORTER

Search NIH funded projects

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

Recent Awards →



Writing Your Application

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!"

Table of Contents

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

NIAID

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 course work 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 thing of the idea before!

NIAID

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

NIAID

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 assess merits of applications, scores each application from “1 – 9”

- Application by Application Discussion:
  - Reviewers with conflicts of interest excused from room
  - Assigned reviewers give their preliminary scores
  - Discussion of applicant’s scientific and technical merit
  - Other panel members join 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 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)

Overall Impact or Criterion Strength	Score	Descriptor
High	1	Exceptional
	2	Outstanding
	3	Excellent
Medium	4	Very Good
	5	Good
	6	Satisfactory
Low	7	Fair
	8	Marginal
	9	Poor

Increased Likelihood of Funding

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

NIAID

Summary Statement (*Example*)

SUMMARY STATEMENT
(Privileged Communication)

PROGRAM CONTACT:
NIH Program Director's Name
Phone Number
Email Address

Release Date: Date/Month/Year

Application Number: 1 K22 AI000000 - 01

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
PCC:

Project Title: Title of Your Proposal

SRG Action: Impact Score: 25
Next Steps: Visit http://grants.nih.gov/grants/next_steps.htm
Human Subjects: 10-No human subjects involved
Animal Subjects: 30-Vertebrate animals involved - no SRG concerns noted

Project Year	Direct Costs Requested	Estimated Total Cost
1	150,000	162,000
2	100,000	108,000
TOTAL	250,000	270,000

Application Number

1 K08 AI063815-01A1

type — *mechanism* — *institute* — *serial* — *year* — *suffix*

Application Type

1 - New
2 - Competing Continuation
5 - Noncompeting Continuation

Mechanism

R01, R03, R15, K01, F32, etc . . .

Institute

GM (NIGMS), CA (NCI), etc . . .

Serial Number

Sequential numbering of applications submitted to particular Institute

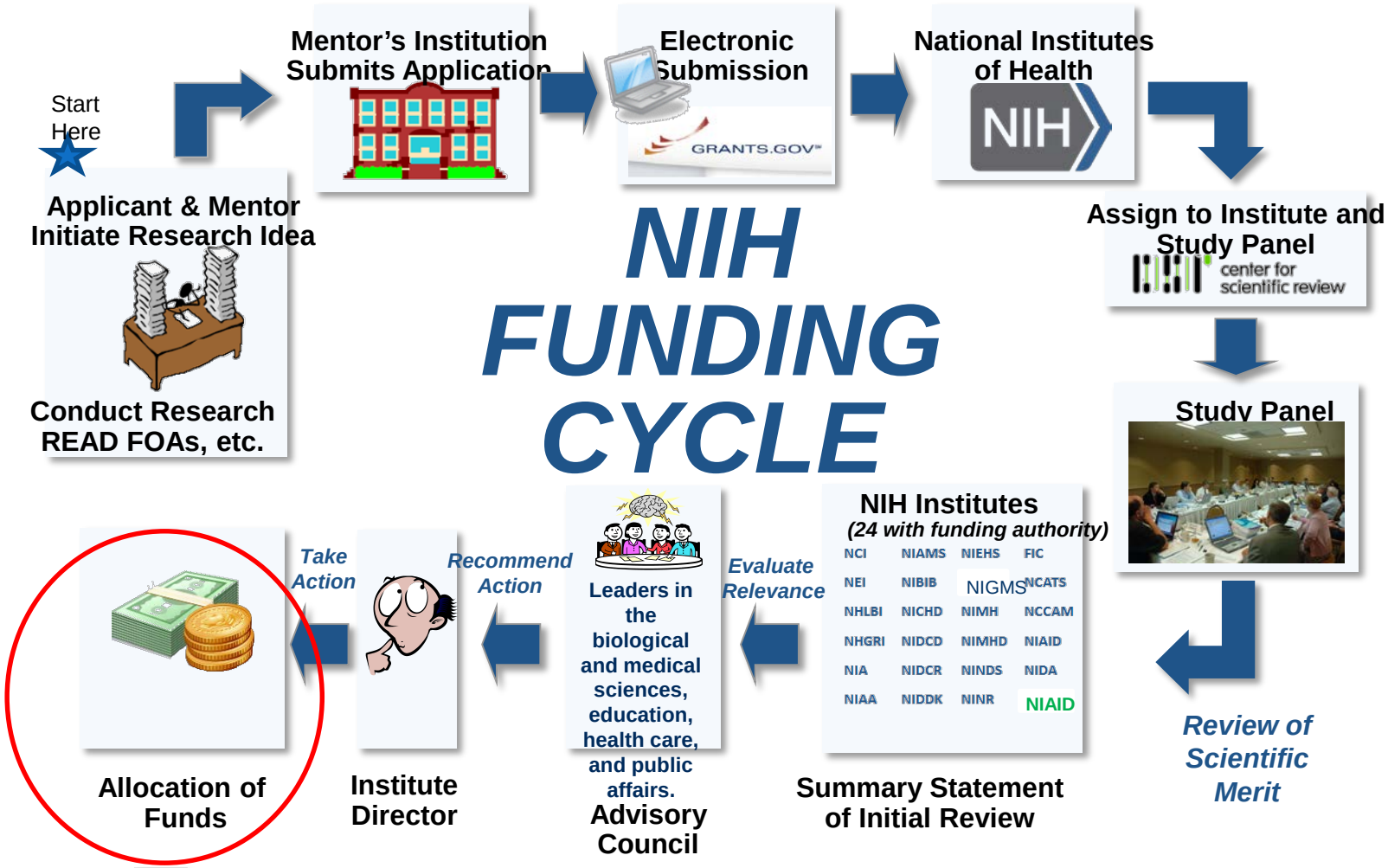
Support Year

All new applications start at -01

Suffix – *additional identifier*

A1 - amended application
S1 - supplement

You Got Funded!



Funded; Now What?

NIAID

You'll Receive a Notice of Award (NoA)

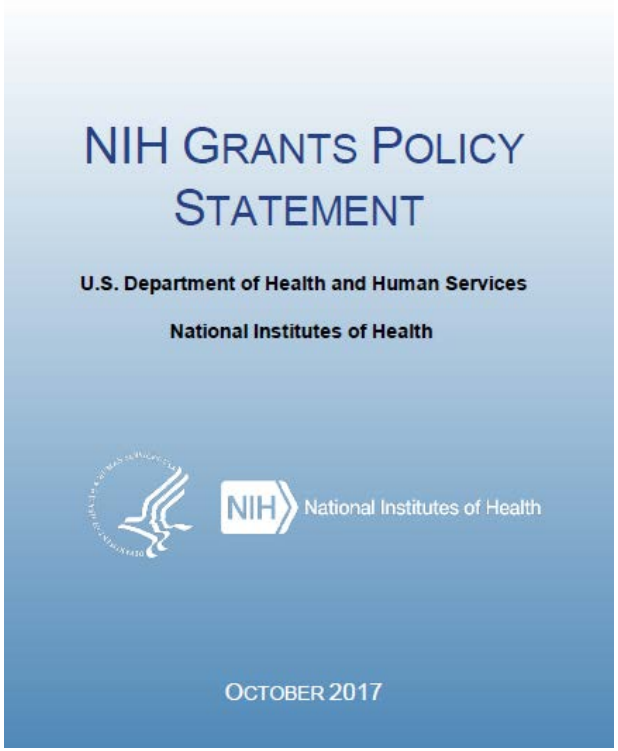
- Legally binding document
  - Award and fiscal information
  - Terms and conditions

- Grantee accepts terms and conditions of award when draws down funds

NIAID

NIH Grants Policy Statement

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



https://grants.nih.gov/policy/nihgps/index.htm

NIAID

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

NIAID

- Your Earlier Questions -

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?

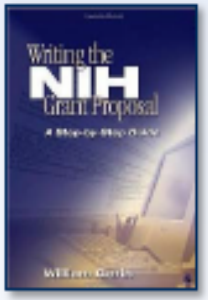
A: Writing (and/or English) not your forte, get help. Numerous books.

NIAID

Manuals & Books

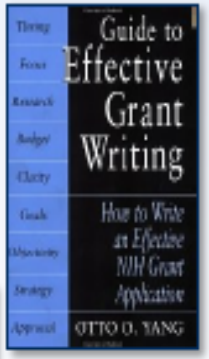
"The Grant Application Writer's Workbook" available at GrantCentral.com

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

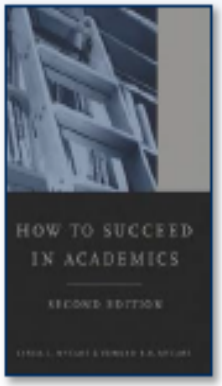


"Grant Application Writers Handbook" (4th Ed)

by Liane Reif-Lehrer

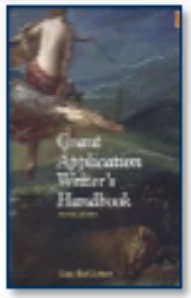


"Guide to Effective Grant Writing: How to Write a Successful NIH Grant Application" by Otto O. Yang



"How to Succeed in Academics"

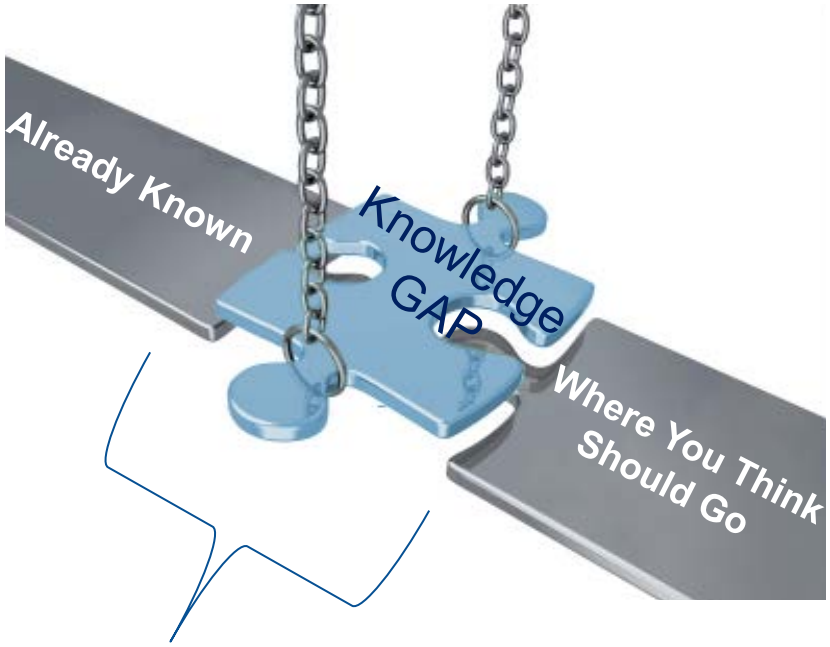
by Edward R. B. McCabe and Linda McCabe



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”

NIAID

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.

NIAID

Additional Questions?

Shawn Drew Gaillard, Ph.D.

Research Training Officer, NIAID, NIH

Shawn.Gaillard@nih.gov

NIAID