# Navigating the NIH and the Peer Review Process

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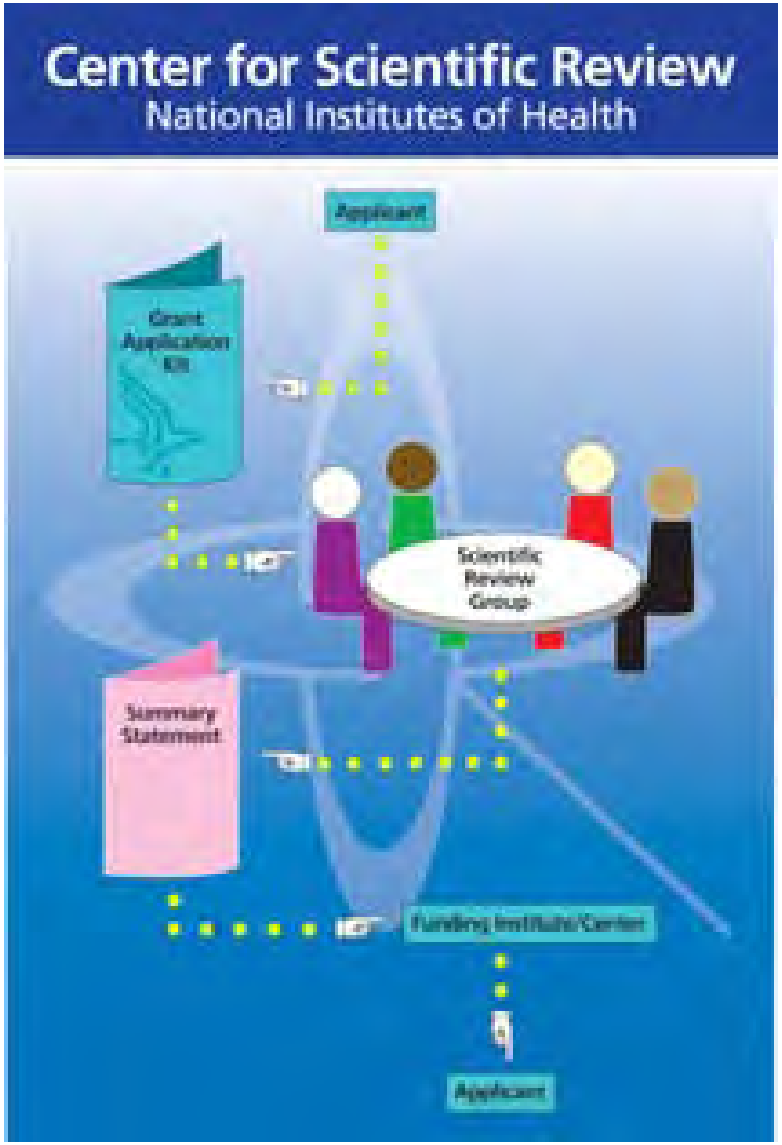
*Some slides adapted from NIH Regional Grants Presentations and NIH Data Book*

# National Institutes of Health

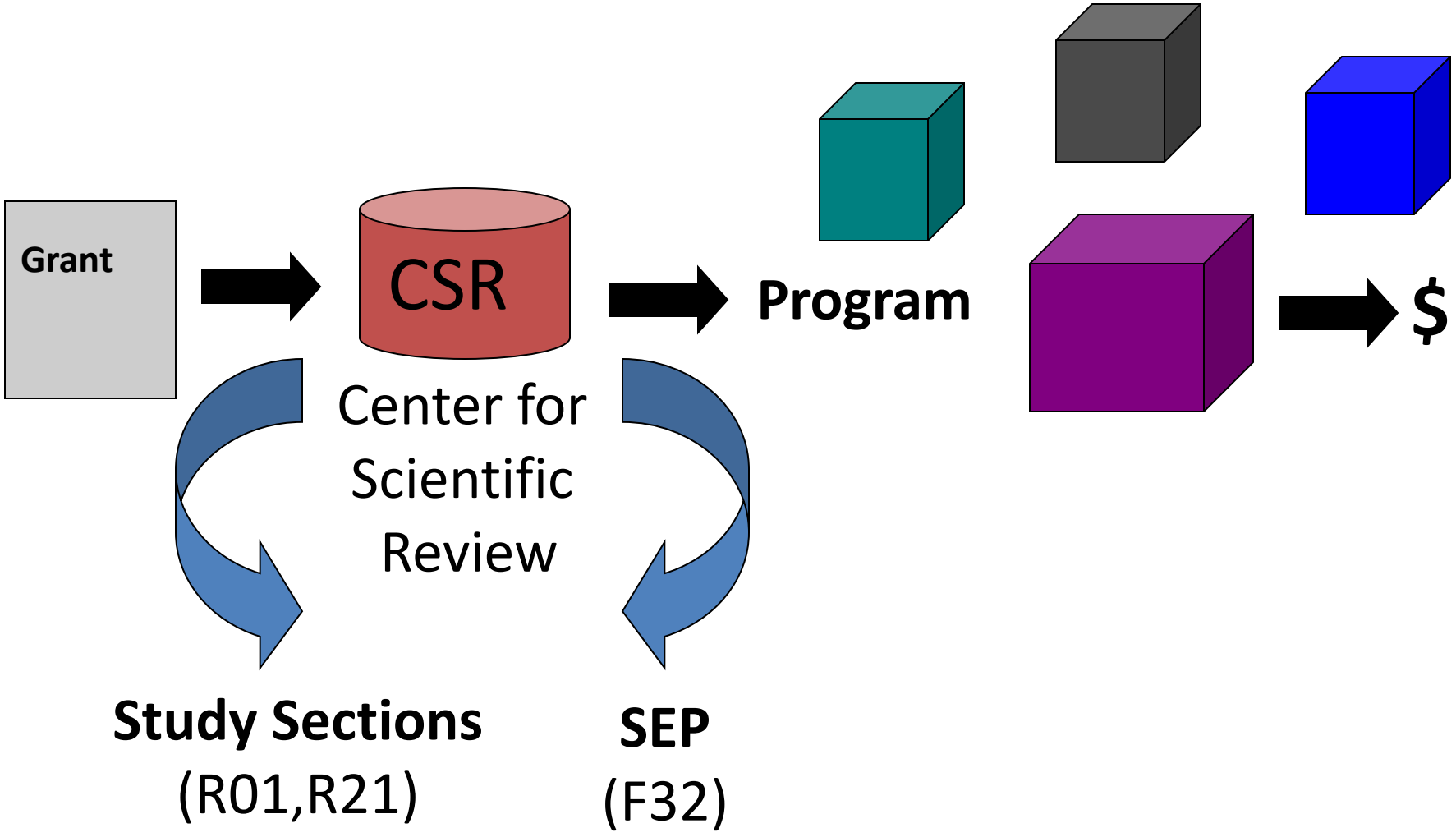
**Office of the Director**
**(Common Fund "Roadmap")**

**21 Institutes**
**(NCI, NIDDK, NHLBI, NIMH etc)**

**6 Centers**
**(CSR, NCRR, CC, etc)**



# National Institutes of Health



# NIH Institutes and Centers

**NIH is one of 11 agencies in the Department of Health and Human Services (HHS)**


**NIH includes 27 Institutes and Centers (ICs)**

# 63 years of Study Sections

The First NIH Study Section

1946

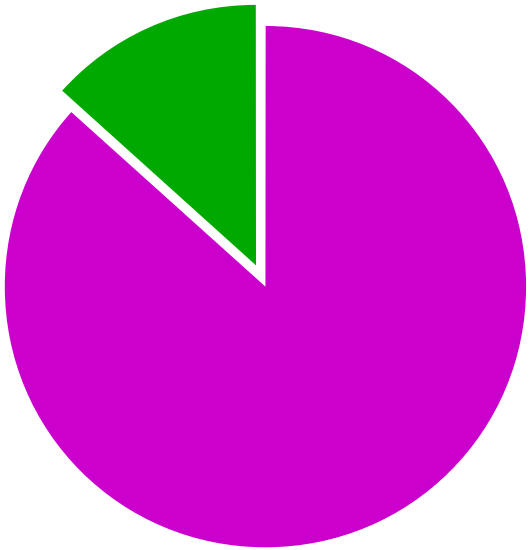
A NIH Study Section Today

2010

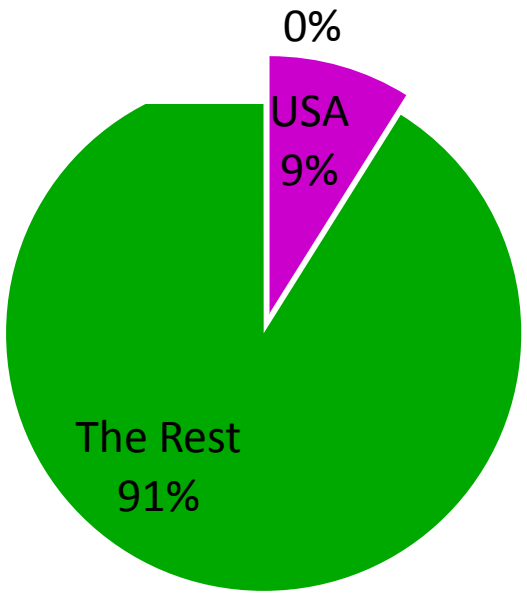
# Why Has U.S. Biomedical Research Been So Successful?

- It is not the money but the way it is spent

**% of Nobel Prizes**
**% of Major Discoveries**



**Global Federal Expenditure for Biomedical Research in Developed Countries**



# 30 Years of Medical Innovation

- MRI and CT Imaging
- ACE inhibitors
- Angioplasty
- Statins
- Mammography
- Coronary Interventions
- H  inhibitors and H2 Blockers
- Antidepressant
- Cataract and Lens Replacement
- Ultrasound Imaging
- Asthma Treatment
- Cardiac Enzymes
- Fluoroquinolones
- Hypoglycemic Agents
- HIV Testing and Intervention
- Tamoxifen
- PSA
- H. Pylori Test and Treatment
- Cephalosporins
- Calcium Blockers
- Conscious Sedation

*Fuchs and Sox, Health Affairs, 20, 30-42*

# The Fundamental Tenets for NIH (1946)

1. The only possible source for adequate support of our medical research is the taxing power of the federal government.

2. The federal government  and politicians must assure complete freedom for individual scientists in developing and conducting their research work.

3. Reviews should be conducted by outside experts essentially without compensation.

4. Program management and review functions should be separated.

Surgeon General Thomas Parran, Jr.

# The Basic Operating Principles of NIH Peer Review

NIH has ownership of the process

- The Scientific Review Officer nominates the review panel, assigns applications and is responsible for the meeting

The study section (SRG, review panel) has ownership of the science.

- Is composed of the best and most experienced scientists in the field). Usually 20 are permanent members, serving 4 years 3 times/year and 10 are ad hoc
- CSR has over 800 study sections reviewing different biomedical science

# The Rules and the Results of the Process

- NIH Pays Science not directly Scientists or Institutions
- Researchers are “Contractors” who bid in an open competition
- Peer Review is the judge of the competition
- Universities and Research Institutions receive funds only to the extent they have competitive Faculty

# NIH Review Process

Initiate Research Idea

Submit Application

Revise/Resubmit

Allocate Funds

National Institutes of Health
Center for Scientific Review

Assign to IC IRG (Study Section)

Study Section

Review for Scientific Merit

Institute

Evaluate for Relevance

Advisory Councils and Boards

Recommend Action

Institute Director

Takes final action

# *The NIH Peer Review Process*

## Scientific Review Group (SRG)

**"Study Section"**

- **Expertise**
- **Stature in field**
- **Mature judgment**
- **Impartiality**
- **Geographical balance**
- **Diversity**

**"Chartered" Permanent or membership**

**"Special Emphasis Panel" (SEP) – ad hoc membership**

# *The NIH Peer Review Process*

## Reviewer Assignments

- **At least three qualified reviewers per application (2 + 1)**
- **Based on scientific content of application**
- **Expertise of reviewer**
- **Suggestions from PI on types of expertise – *not names!***
- **Suggestions from Program staff**

# The Study Section

- 15 to 18 regular members and as many as 5 or 6 ad hoc members
  - Members have their own R01s
- Meets 3 to 4 times a year
- Review from 50 to 120 proposals per session
- Reviewers are paid ~$200 per day

# The Meeting

- SRA introduces the grant
- Those with conflict leave the room
- Primary, secondary and tertiary reviewers verbalize their priority scores
- Reviewers provide their comments
- Reviewers recapitulate their scores
- Study section members mark vote (may be asked to announce if they are outside the range)

Video of a mock study section: http://www.youtube.com/watch?v=fBDxI6l4dOA&feature=youtu.be

# What determines the score

- The quality of the grant
- The reviewers

What determines the reviewer:

- The Study Section
- Luck

# Enhancing Peer Review

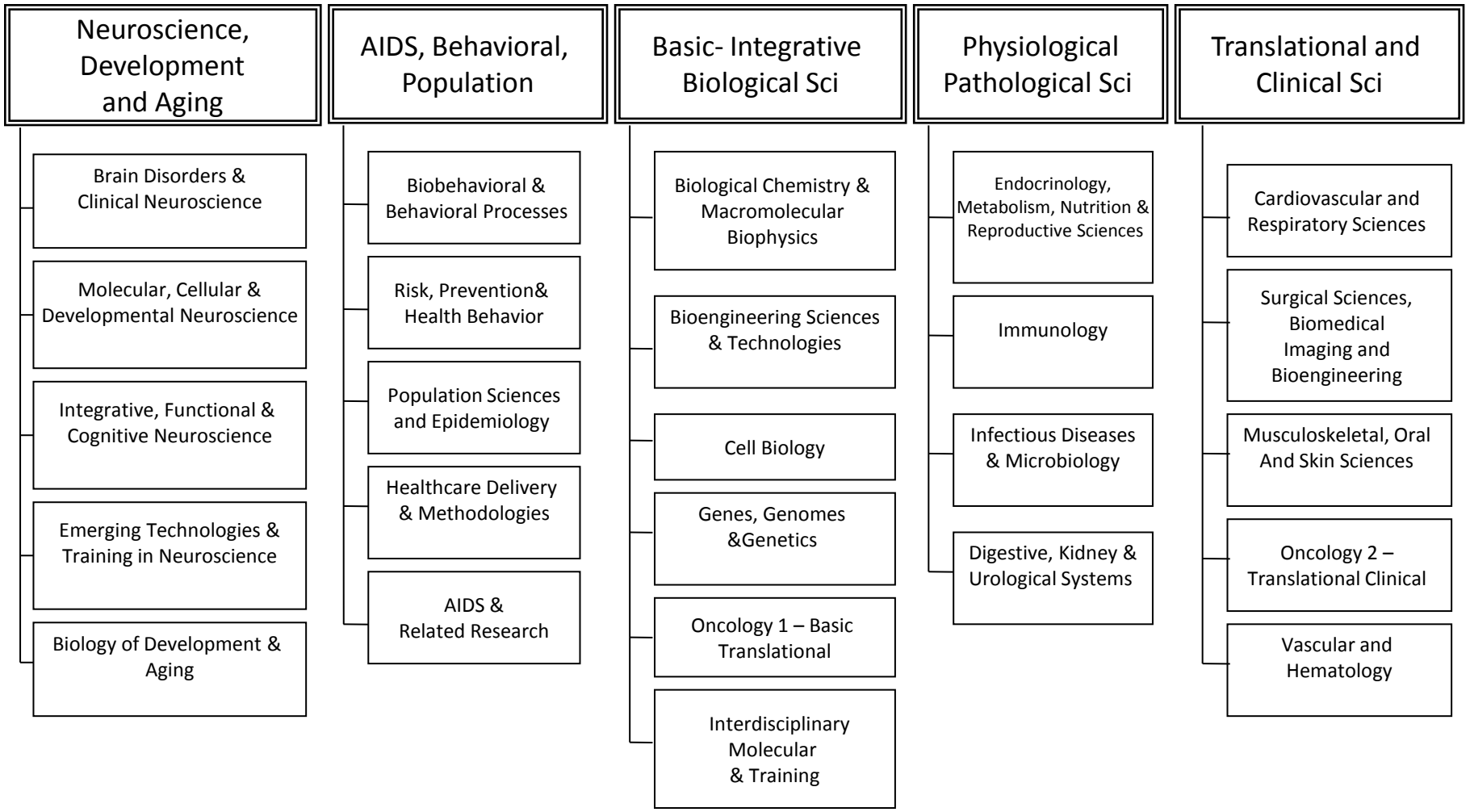
# Major Complaints About NIH Peer Review

- The process is too slow
- There are not enough senior/experienced reviewers
- The process favors predictable research instead of significant, innovative, or transformative research
- Clinical research may not fare as well as other research
- The time and effort required to write, submit, resubmit, review and re-review is a heavy burden on applicants and reviewers

# Enhancing Peer Review

1. Reorganizing CSR and Recruiting Staff
2. Improving Study Section Alignment
3. Assigning Applications More Accurately
4. Addressing Review and Funding for New Investigators
5. Shortening the Review Cycle
6. Advancing Additional Review Platforms
7. Recruiting the Best Reviewers

# The reorganized CSR

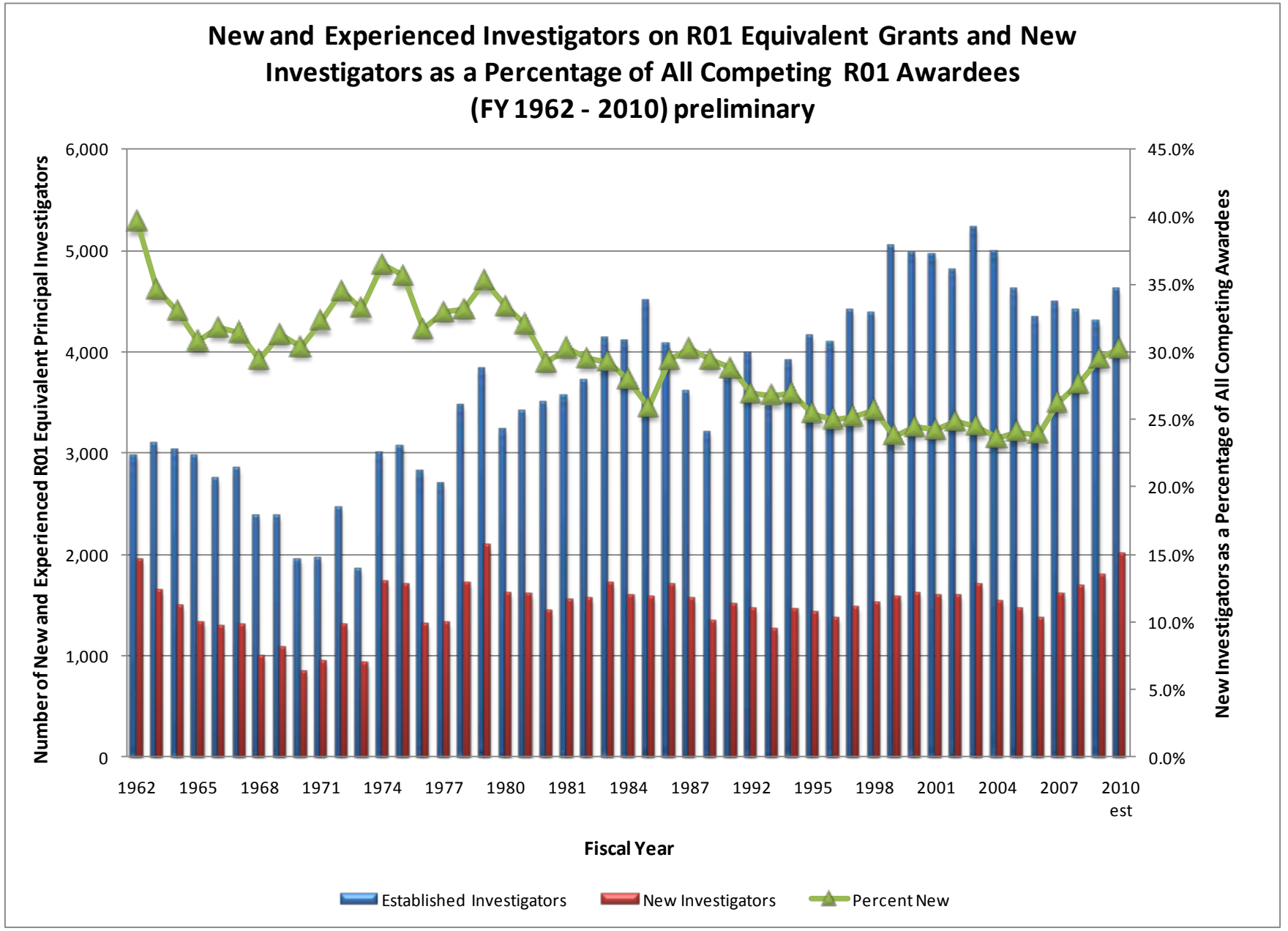


# Enhancements to peer review at study section

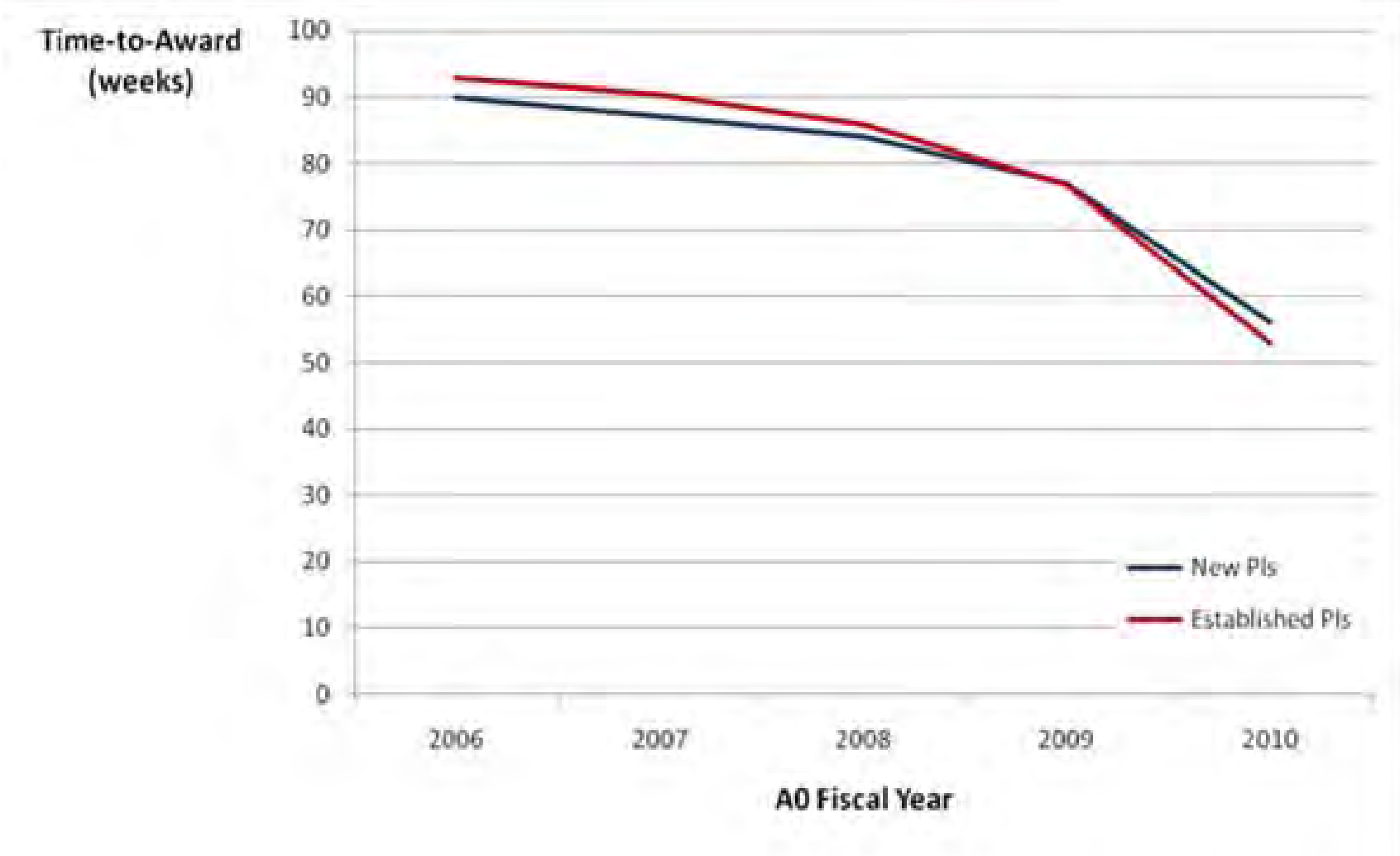
New investigators are reviewed first

Then applications are reviewed based on their priority score

Some institutes add 5 or 10% to the percentile score for first-time investigators


New and Experienced Investigators on R01 Equivalent Grants and New Investigators as a Percentage of All Competing R01 Awardees
(FY 1962 - 2010) preliminary
Number of New and Experienced R01 Equivalent Principal Investigators
New Investigators as a Percentage of All Competing Awardees
6,000
5,000
4,000
3,000
2,000
1,000
0
45.0%
40.0%
35.0%
30.0%
25.0%
20.0%
15.0%
10.0%
5.0%
0.0%
1962
1965
1968
1971
1974
1977
1980
1981
1984
1987
1992
1995
1998
2001
2004
2007
2010 est
Fiscal Year
Established Investigators
New Investigators
Percent New

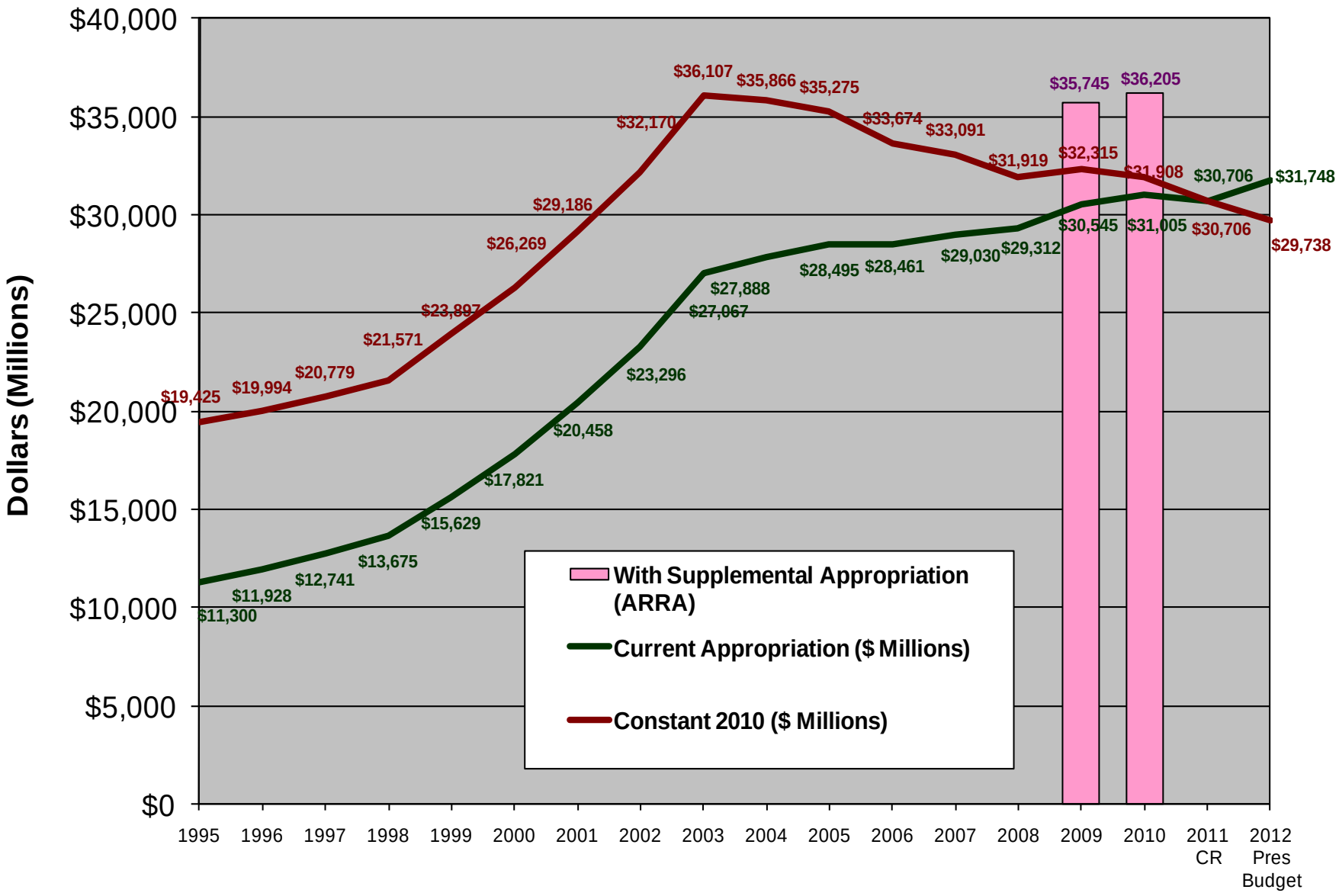
# 2. Funding the Most Promising Research Earlier



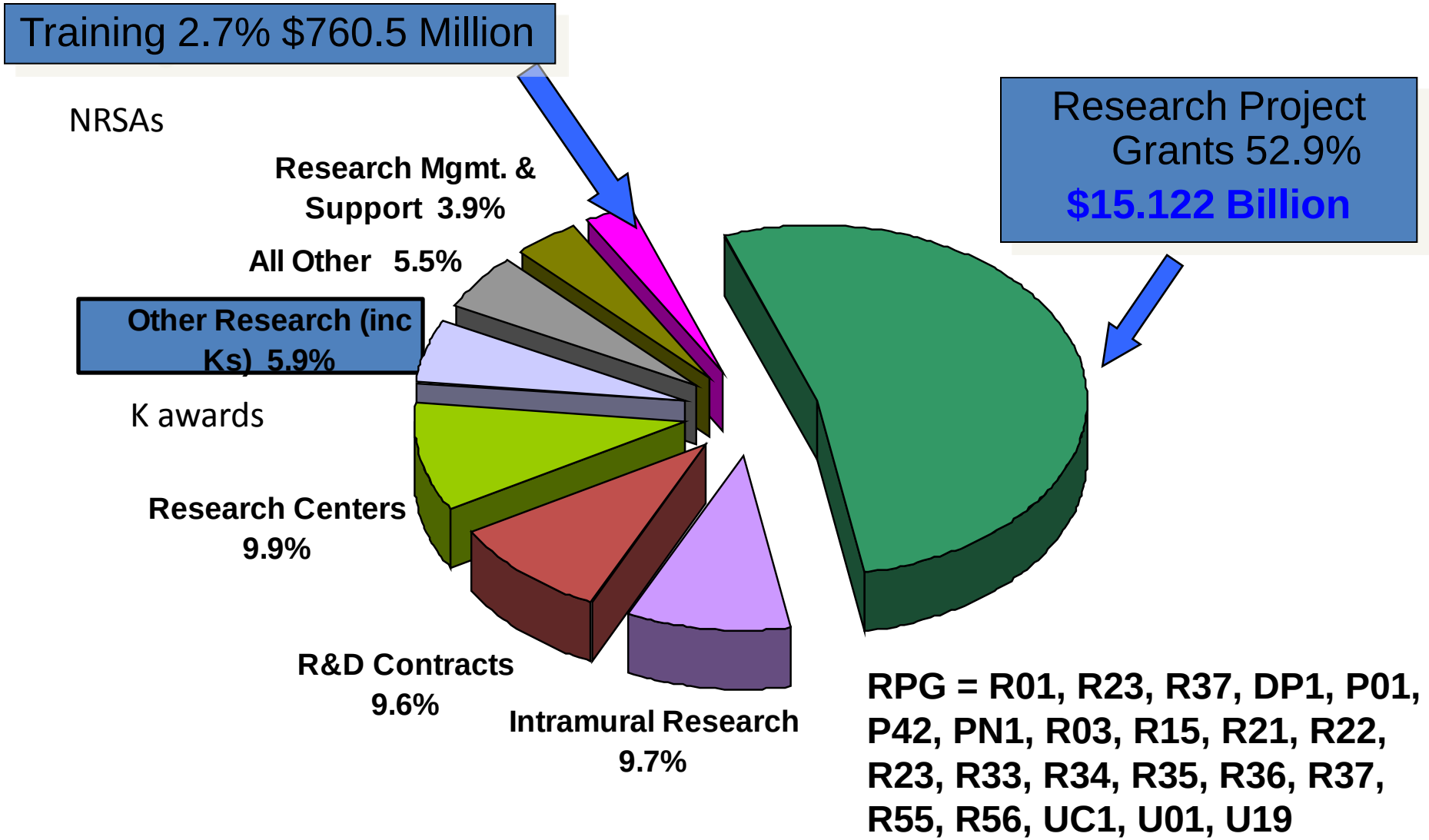
# Focusing More on Impact and Significance and Less on Approach

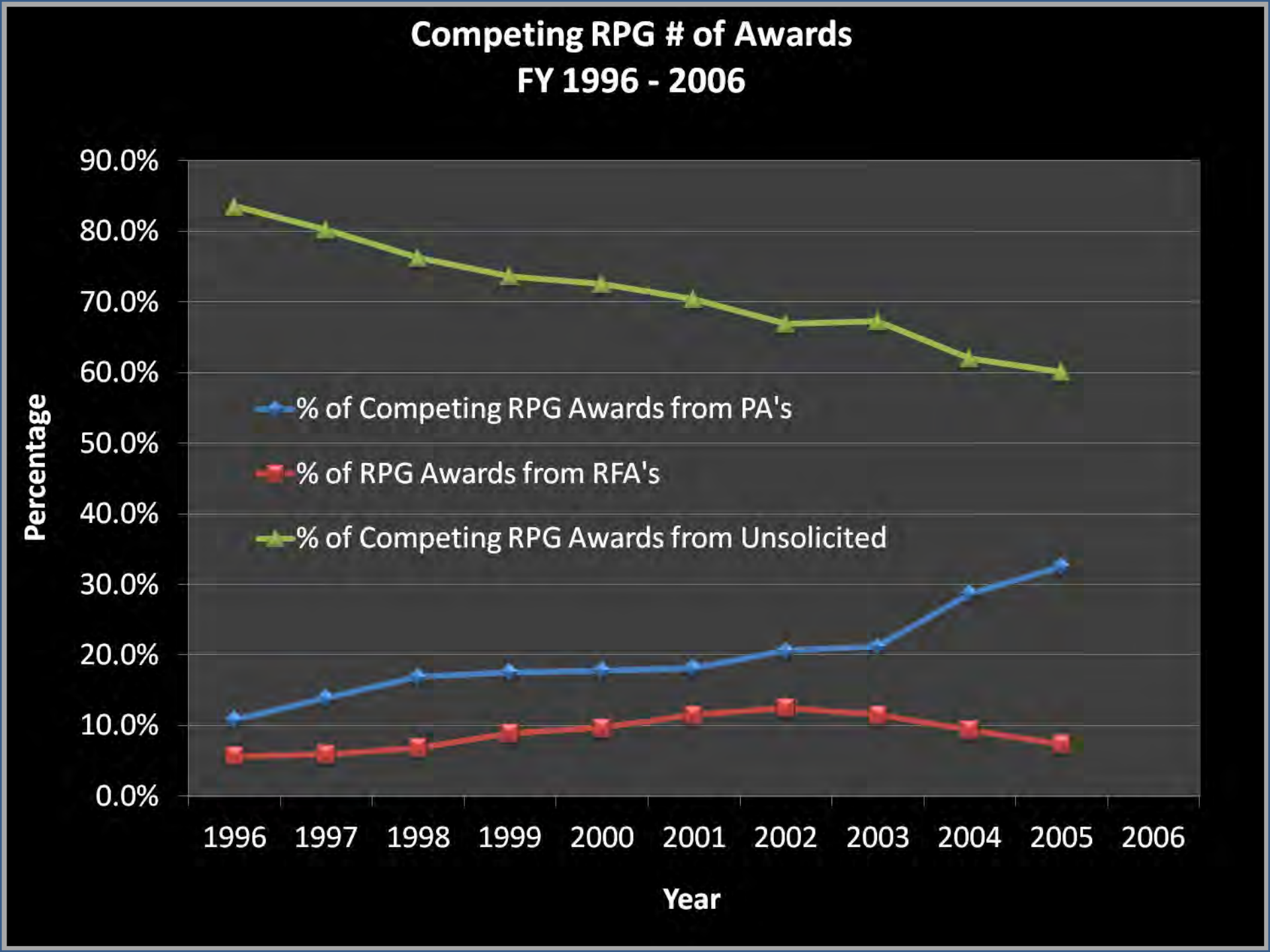
- Shorten Applications (13 or 7 pages instead of 25 or 12)
- Scoring Significance
- Discussed applications receive additional overall impact score
- Training of Reviewers and Chairs

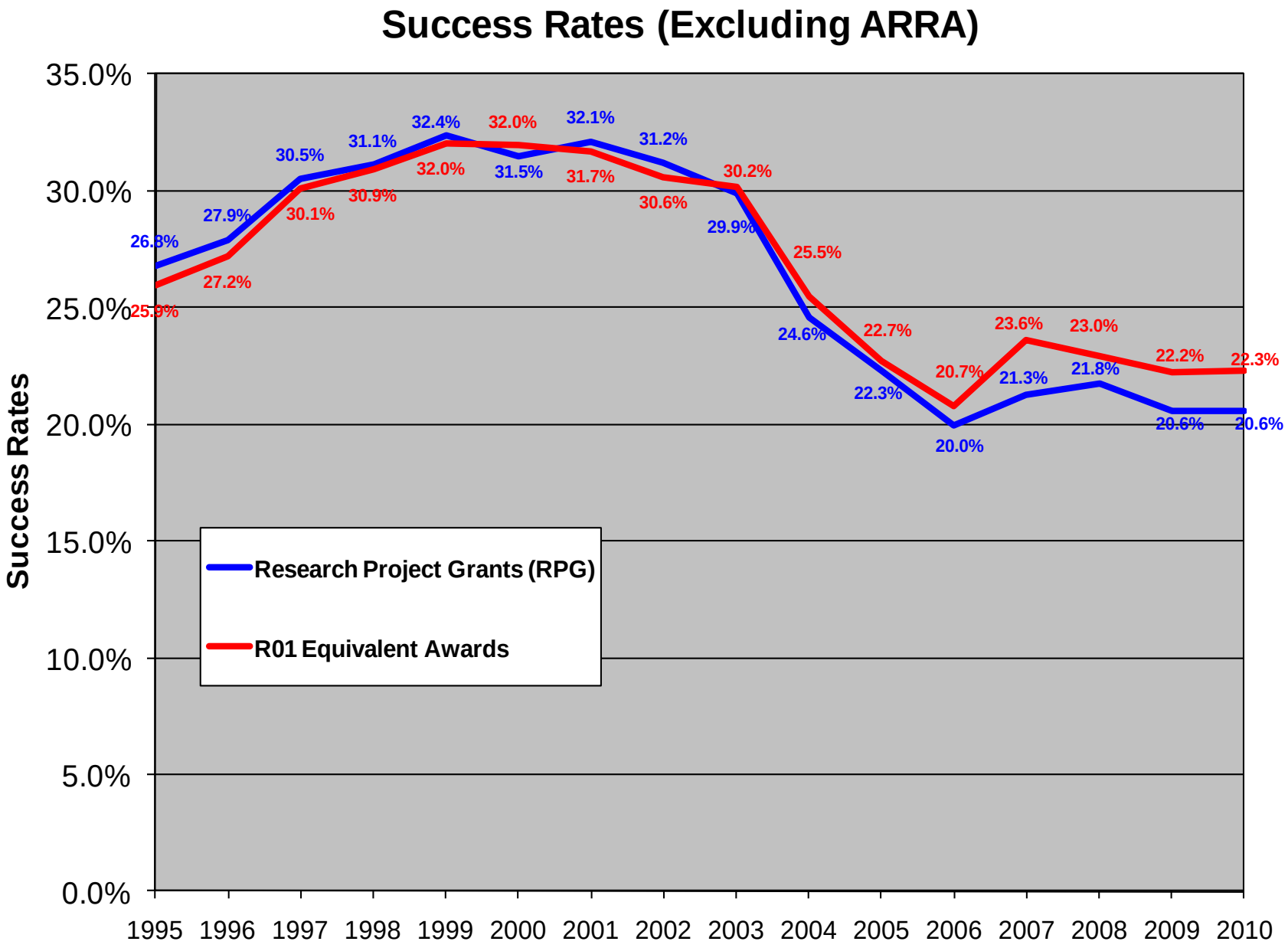
# NIH Funding


NIH Budget in Current and Constant Dollars
Dollars (Millions)
$40,000
$35,000
$30,000
$25,000
$20,000
$15,000
$10,000
$5,000
$0
1995
1996
1997
1998
1999
2000
2001
2002
2003
2004
2005
2006
2007
2008
2009
2010
2011 CR
2012 Pres Budget
$19,425
$19,994
$20,779
$21,571
$23,897
$26,269
$29,186
$32,170
$36,107
$35,866
$35,275
$33,674
$33,091
$31,919
$32,315
$31,908
$30,706
$29,738
$11,300
$11,928
$12,741
$13,675
$15,629
$17,821
$20,458
$23,296
$27,067
$27,888
$28,495
$28,461
$29,030
$29,312
$30,545
$31,005
$30,706
$31,748
$35,745
$36,205
With Supplemental Appropriation (ARRA)
Current Appropriation ($ Millions)
Constant 2010 ($ Millions)

# FY 2007 Estimate
# Total NIH Budget Authority
# $28.578 Billion

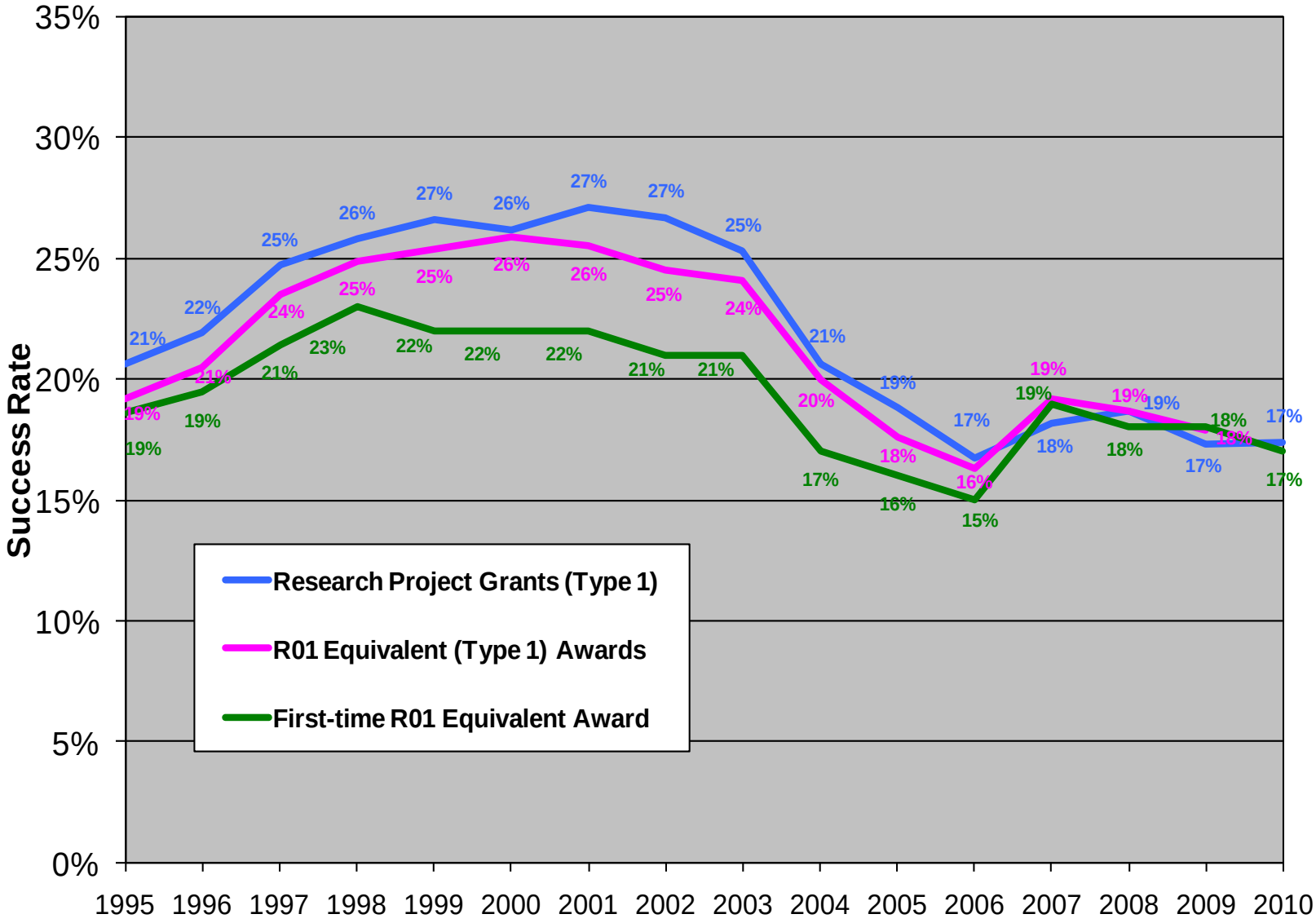



Competing RPG # of Awards
FY 1996 - 2006
90.0%
80.0%
70.0%
60.0%
50.0%
40.0%
30.0%
20.0%
10.0%
0.0%
Percentage
% of Competing RPG Awards from PA's
% of RPG Awards from RFA's
% of Competing RPG Awards from Unsolicited
1996
1997
1998
1999
2000
2001
2002
2003
2004
2005
2006
Year


Success Rates (Excluding ARRA)
Success Rates
35.0%
30.0%
25.0%
20.0%
15.0%
10.0%
5.0%
0.0%
1995 1996 1997 1998 1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010
26.8% 27.9% 30.5% 31.1% 32.4% 31.5% 32.1% 31.2% 29.9% 24.6% 22.3% 20.0% 21.3% 21.8% 20.6% 20.6%
25.9% 27.2% 30.1% 30.9% 32.0% 32.0% 31.7% 30.6% 30.2% 25.5% 22.7% 20.7% 23.6% 23.0% 22.2% 22.3%
Research Project Grants (RPG)
R01 Equivalent Awards

FASEB

# Success Rates for New (Type 1) Applications, Including First-time R01 Award

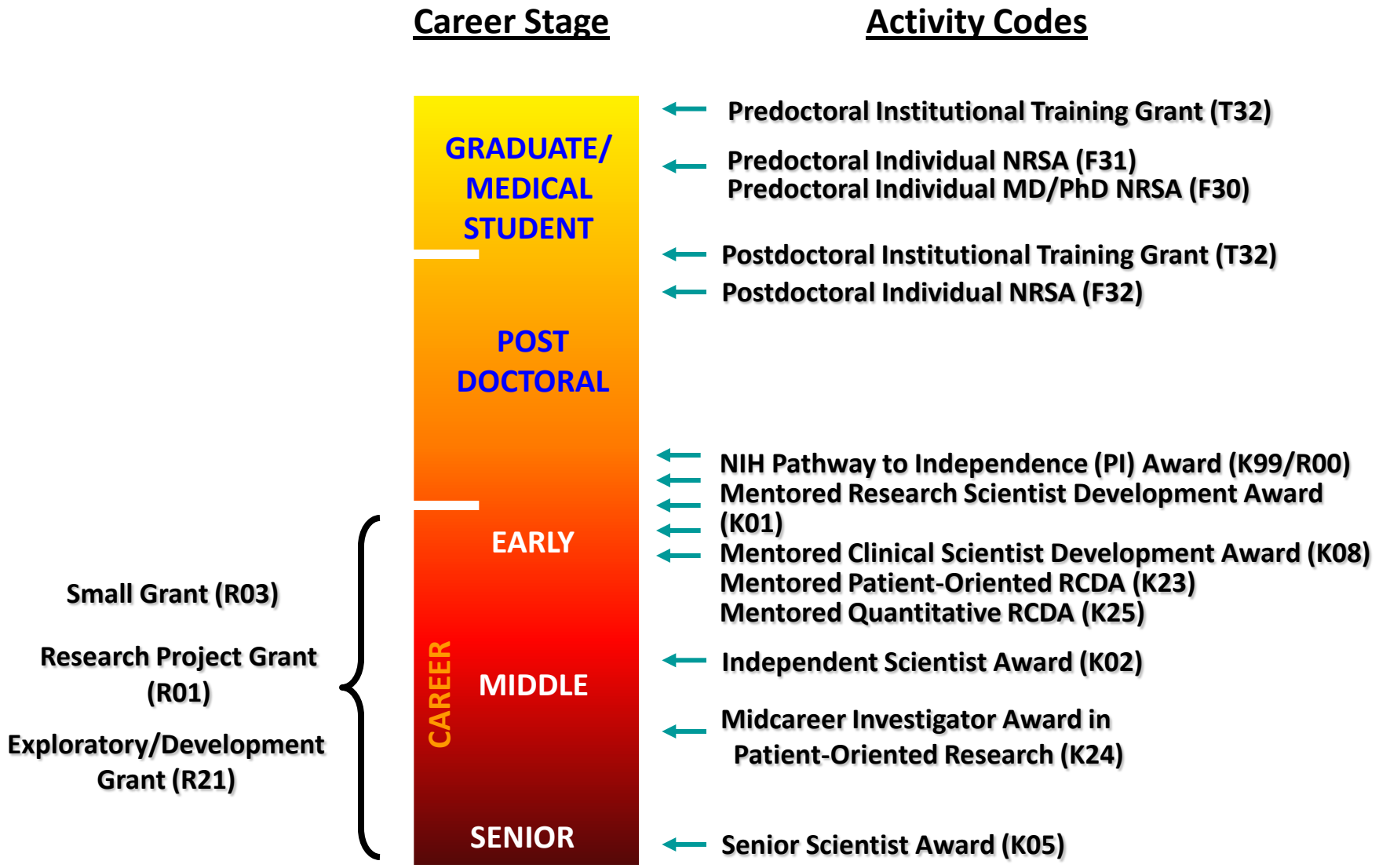



FASEB

# How to find your way through the NIH funding process

seek out mentors and advice

# NIH Training and Career Development Timetable



# NIMH National Institute of Mental Health

Reducing the burden of mental illness and behavioral disorders through research on mind, brain, and behavior



## About NIMH

Funds go to research priorities

### Vision

NIMH supports innovative science that will profoundly transform the diagnosis, treatment, and prevention of mental disorders, paving the way for a cure.

### Mission

The NIMH mission is to reduce the burden of mental illness and behavioral disorders through research on mind, brain, and behavior. **To fulfill its mission, the Institute is committed to the following priorities:**

- support the integrative science of brain and behavior providing the foundation for understanding mental disorders;
- define the genetic and environmental risk architecture of mental disorders;
- develop more reliable, valid diagnostic tests and biomarkers for mental disorders;
- develop more effective, safer, and equitable treatments that have minimal side-effects to reduce symptoms, and improve daily functioning;
- support clinical trials that will provide treatment options to deliver more effective personalized care across diverse populations and settings; and
- create improved pathways for rapid dissemination of science to mental health care and service efforts.

To reach these goals, the NIMH divisions and programs are designed to emphasize translational research spanning bench, to bedside, to practice. For targeted priorities and funding initiatives, please visit our division websites

**Director's Corner**
Director's Updates, Institute news, articles, and links of interest from NIMH Director, Dr. Thomas Insel

**Strategic Planning Reports**
Priorities and strategic plans for achieving the NIMH mission

**Connect with NIMH**
Employment opportunities, contact information, directions, directories, and Gift Fund contributions

**Organization**
Activities and focus of NIMH offices, divisions, branches, and programs

**Advisory Boards & Groups**
The National Advisory Mental Health Council, Board of Science Counselors, [illegible] Review Committees

**Budget**
Annual budget requests to Congress for research funding

### Director's Updates

- Institute of Medicine (IOM) of the National Academies Announces New Members
- NIH Director's Pioneer Awards and New Innovator Awards: Funded Work Includes Research that May Increase Knowledge about Mental Health and Brain Disease
- NIMH Perspective on Diagnosing and Treating Bipolar Disorder in Children
- More Director's Updates...

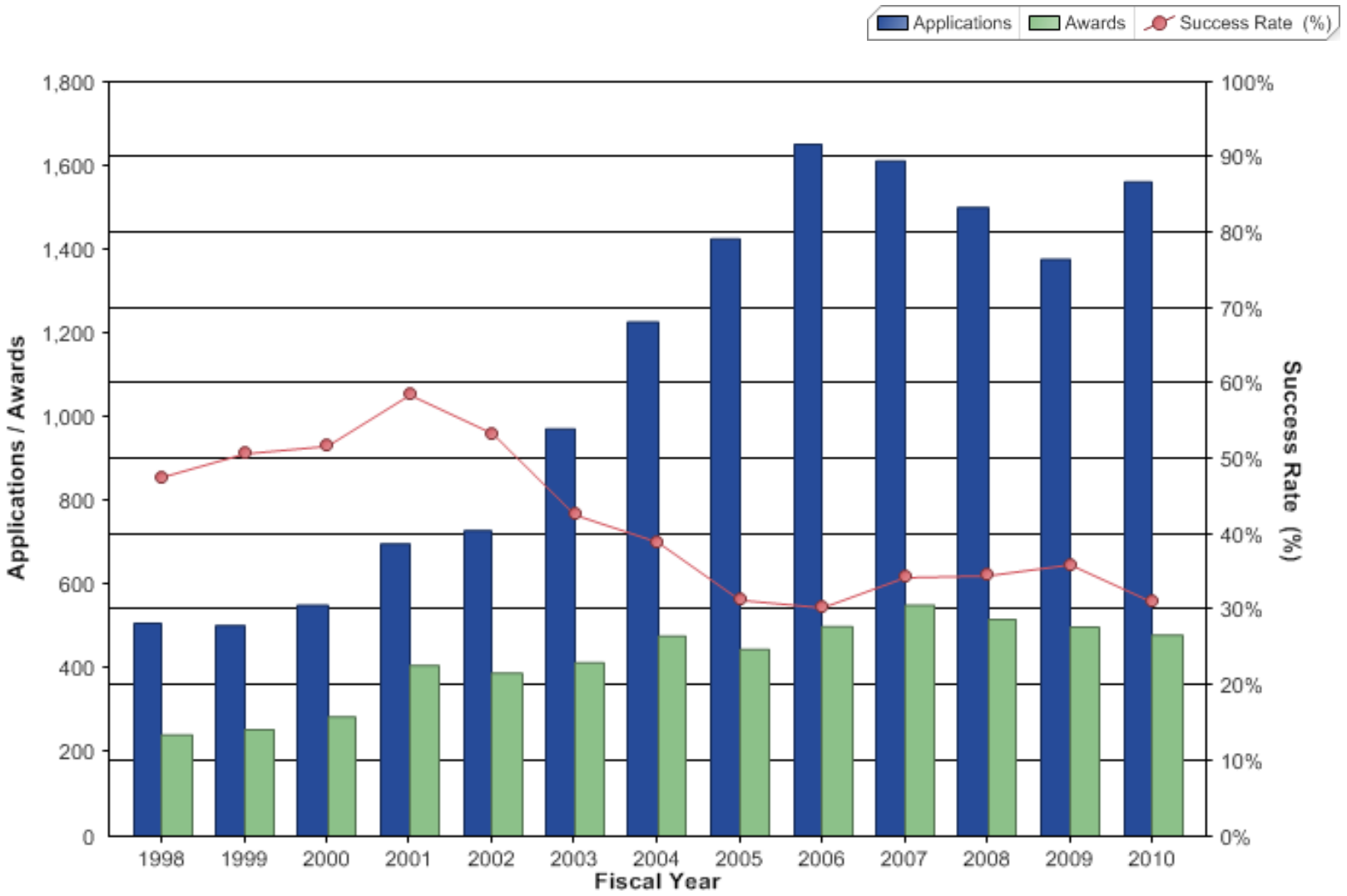
### Offices and Divisions

- Office of the NIMH Director
- Division of Neuroscience and Basic Behavioral Science (DNBBS)
- Division of Adult Translational Research and Treatment Development (DATR)
- Division of Developmental Translational Research (DDTR)
- Division of AIDS and Health and Behavior Research (DAHBR)
- Division of Services and Intervention Research (DSIR)
- Division of Extramural Activities
- Division of Intramural Research Programs (DIRP)

# Success rates for Career Development

- F30:  MD-PhD Fellowships (33%)
- F32: Postdoctoral Fellowships (30%
- K22:  Postdoctoral ⇨ Faculty (23%)
- K99:  Postdoctoral ⇨ Faculty (23%)
- K01:  Research Scientist (39%)
- K08: Clinician Scientist (44%)
- K23:  Patient-Oriented (38%)

Kirschstein-NRSA pre-doctoral fellowships (F31s)
Applications, awards, and success rates



# Understanding the Institute's Mission

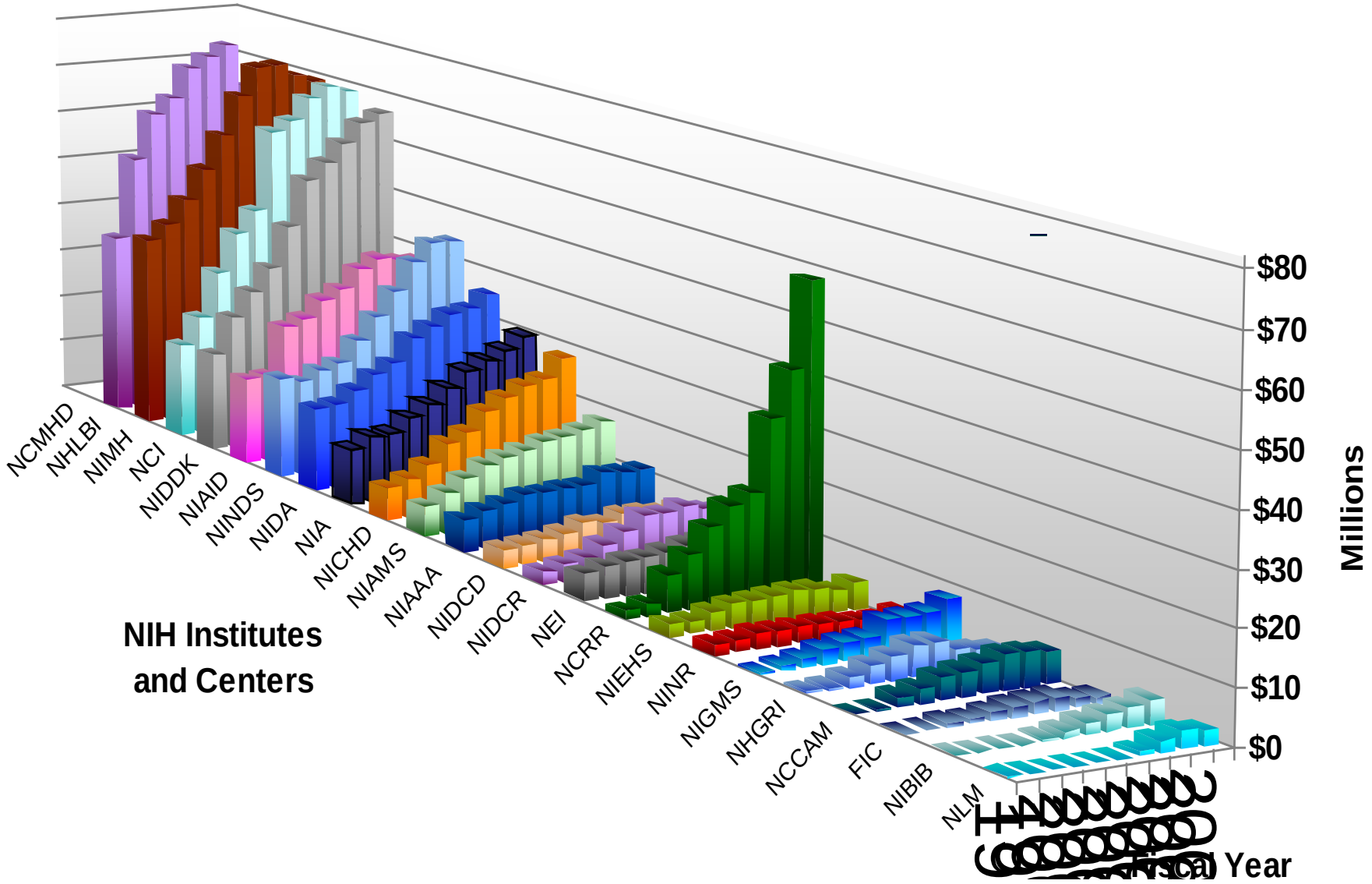
- Mission of each NIH Institute is based and defined in law
  - Authorizations (periodic)
  - Appropriations (annual)
- ICs establish specific research emphases
  - Legislative mission
  - Current state of science
- *Use the Web to find out!*

# Not every institute funds all types of NRSAs!

Read the program announcement (PA)

- Search for relevant PA at http://grants.nih.gov/grants/guide/index.html

# Trends in funding individual NIH K awards by institute or center



# Planning a grant

- What type? - training vs. research
- What agency?
  - NIH – F, K, R type awards
    - RFA, PA
  - Private Foundations
  - Other government agencies - DOD, etc

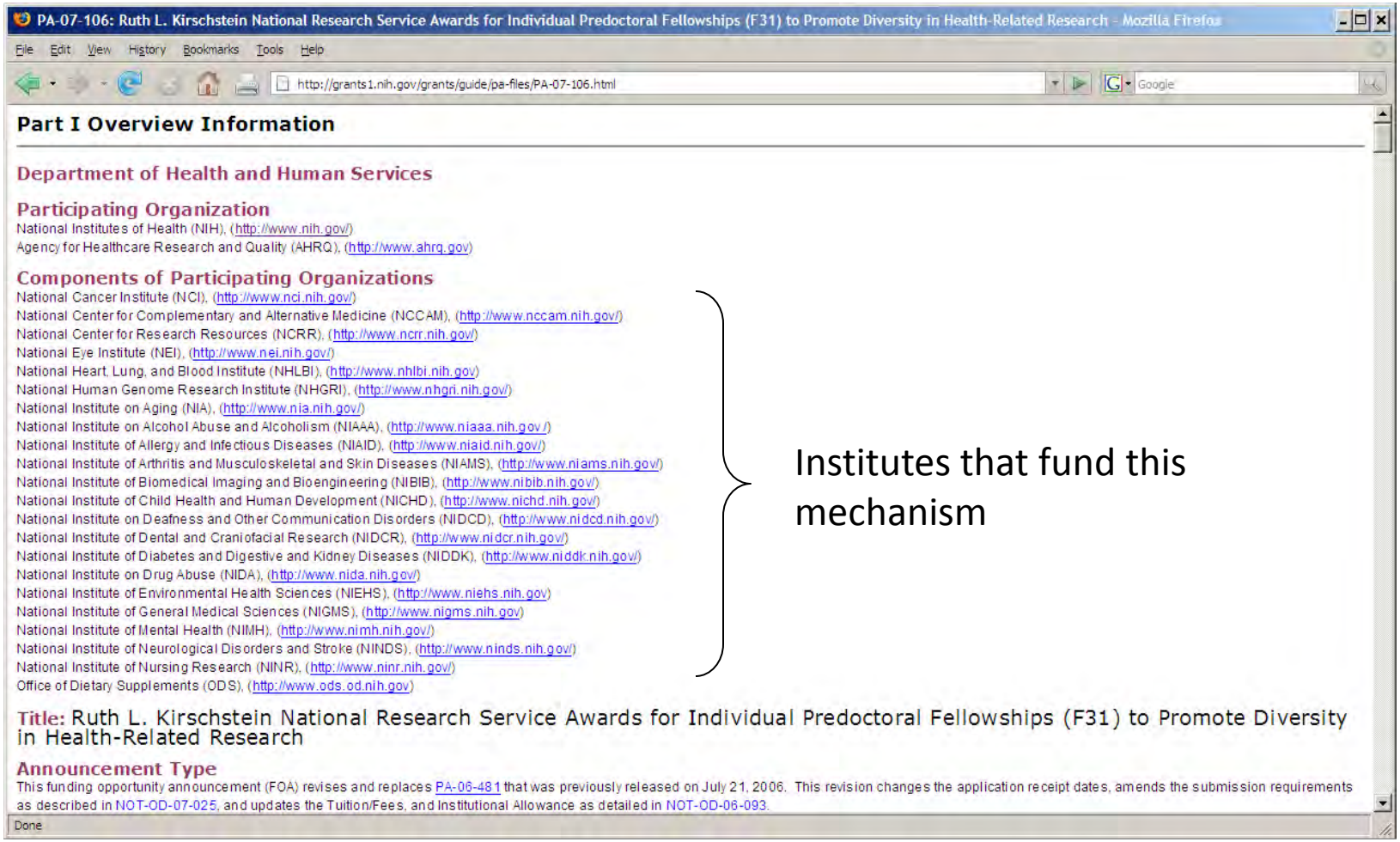
# Know what the agency wants

- What is more important for this grant - training or research?
- Gear the grant to address the specific issues the agency is trying to address
- Consider submitting the grant to more than one agency (only if appropriate!!)
  - Note:  More is not necessarily better!!

# The NIH grant

- PHS Form 398 - FOLLOW THE DIRECTIONS!
- www.nih.gov go to CSR for study sections
  - Ask for advice
- "NIH Peer Review Revealed" and "NIH Tips for Applicants" videos
- Don't be afraid to contact the NIH staff
  - Scientific Review Administrator/Scientific Review Officer - CSR
  - Program Officer - Institutes

# Program Announcement (PA)




Institutes that fund this mechanism

# K Kiosk - Information about NIH Career Development Awards

- Career Award Wizard - Helps you select the right career award
- **Visual Guide to NIH Career Development Awards**
  - For individuals with a research doctorate
  - For individuals with a health-professional doctorate
- **Career Award Data and Administrative Information**
  - Funded Career Development Awards
  - Career Award Application Success Rates

| Program | Description |
|---|---|
| K01 | Mentored Research Scientist Development Award<br>Career development in a new area of research.<br>3-5 yrs; Salary determined by the sponsoring Institute.<br><br>International Research Scientist Development K01 Award (IRSDA)<br>Provides US scientists with the opportunity to embark/enhance research careers related to global health.<br><br>Mentored Career Development Award to Promote Faculty Diversity in Biomedical Research (K01) - NHLBI (RFA-HL-05-015)<br>Mentored Career Award for Faculty at Minority Institutions (K01) - NHLBI (RFA-HL-05-016) |

# Components: Research Grant

- Abstract
- Specific aims
- Research strategy (+ preliminary data)
  - Significance (overall or for each aim)
  - Innovation (overall or for each aim)
  - Approach

# Components: Training Grant

- Often same as research grant PLUS
- Career development plan
  - Past accomplishments and training (breaks?)
  - Future goals
  - Deficiencies in training - plan to correct
- Sponsor information
  - Track record in training
  - Current support for research in this area

# How career development awards are assessed

- Candidate
  - Evidence of commitment
  - Evidence of research experience
- Career development plan
  - Specificity
- Proposal
  - Reflects on applicant and mentorship
- Mentor
  - NIH funded
  - Mentorship experience
- Evidence of institutional commitment

# Gathering Information

- Monitor Institute websites and the NIH Guide.
- Get to know the Program Officer for your scientific area.
- Contact a PO about your research ideas.
  - Fit with Institute mission and priorities
  - Best grant mechanism or program
  - Appropriate study section for review
- Participate in workshops and symposia.
- Participate in review of grant applications.
- Talk with mentors, collaborators, & peers about ideas for your application.

# Research Portfolio Online Reporting Tool (RePORT)

- A searchable database of federally supported biomedical research – replaced CRISP.
- 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/collaborator.

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

# Remember … *Before you start*

- Talk to program official at appropriate IC

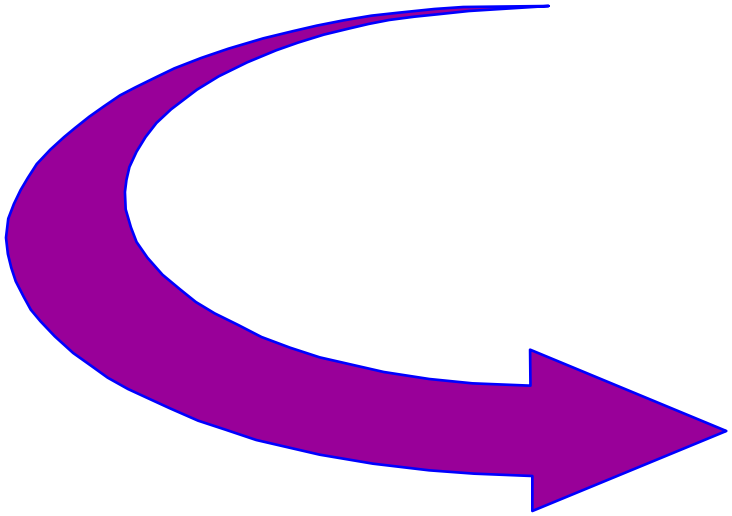
  Find program officers through mentors, colleagues, and the program staff at the Institute or Center that matches your scientific area. Info at http://writedit.wordpress.com/nih-paylines-resources/
- Read instructions for application form
- Know your audience
  - Which study section is most likely to review your application?
- *Propose research about which you are **passionate** and totally committed to doing*

# Dual Review System for Grant Applications

First Level of Review

Scientific Review Group (SRG)

- Provides Initial Scientific Merit
- Review of Grant Applications
- Rates Applications and Makes Recommendations for Appropriate Level of Support and Duration of Award



Second Level of Review

Council

- **Makes Recommendation to Institute Staff on Funding**
- **Evaluates Program Priorities and Relevance**
- **Advises on Policy**

# Principles of Success

- Understand the agency mission
  - *Every IC is different!*
- Secure collaborators (mentors) to complement your expertise and experience
  - Don't compete … *collaborate!*
- Learn and practice the skills of writing applications for grant funds
- Understand the peer review process
- Take control of your life and career!