# Grants 101

July 31, 2015

I. NIH Structure & Behind the Scenes at Study Section
Tom Hawn
II. Introduction to Research Administration at the UW
Monica Fawthrop
III. Training & Career Development Awards
Sheila Lukehart

# Grants 101
# Part I: NIH Structure & Behind the Scenes at a Study Section

**Outline**

1. NIH Structure
    A. Funding Trends
    B. Structure & People at NIH

2. Behind the Scenes at a Study Section

# National Institutes of Health

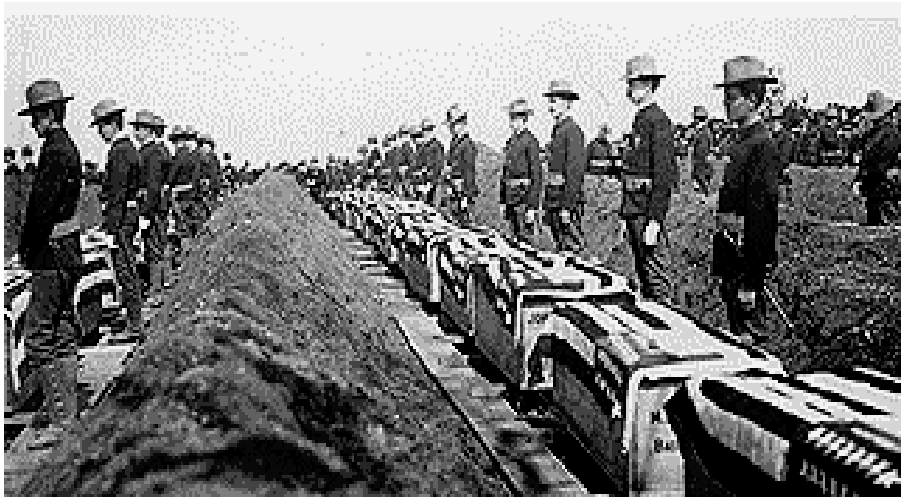
## US Department of Health and Human Services


The Boss

Secretary of H&HS
Sylvia Mathews Burwell


Director of NIH
Francis Collins, MD PhD

# NIH History



## Responses to Yellow Fever

1879
- Yellow fever destroyed the Mississippi Valley
- A $30,000 bid (RFA) from the US Army for Universities
- 1st peer-reviewed applications for research.

1887
- Marine Hospital Service established, NIH roots started
- Director Joseph Kinyoun

1930
- NIH officially named

Adapted from slide From Toni Scarpa, head NIH CSR

# 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.

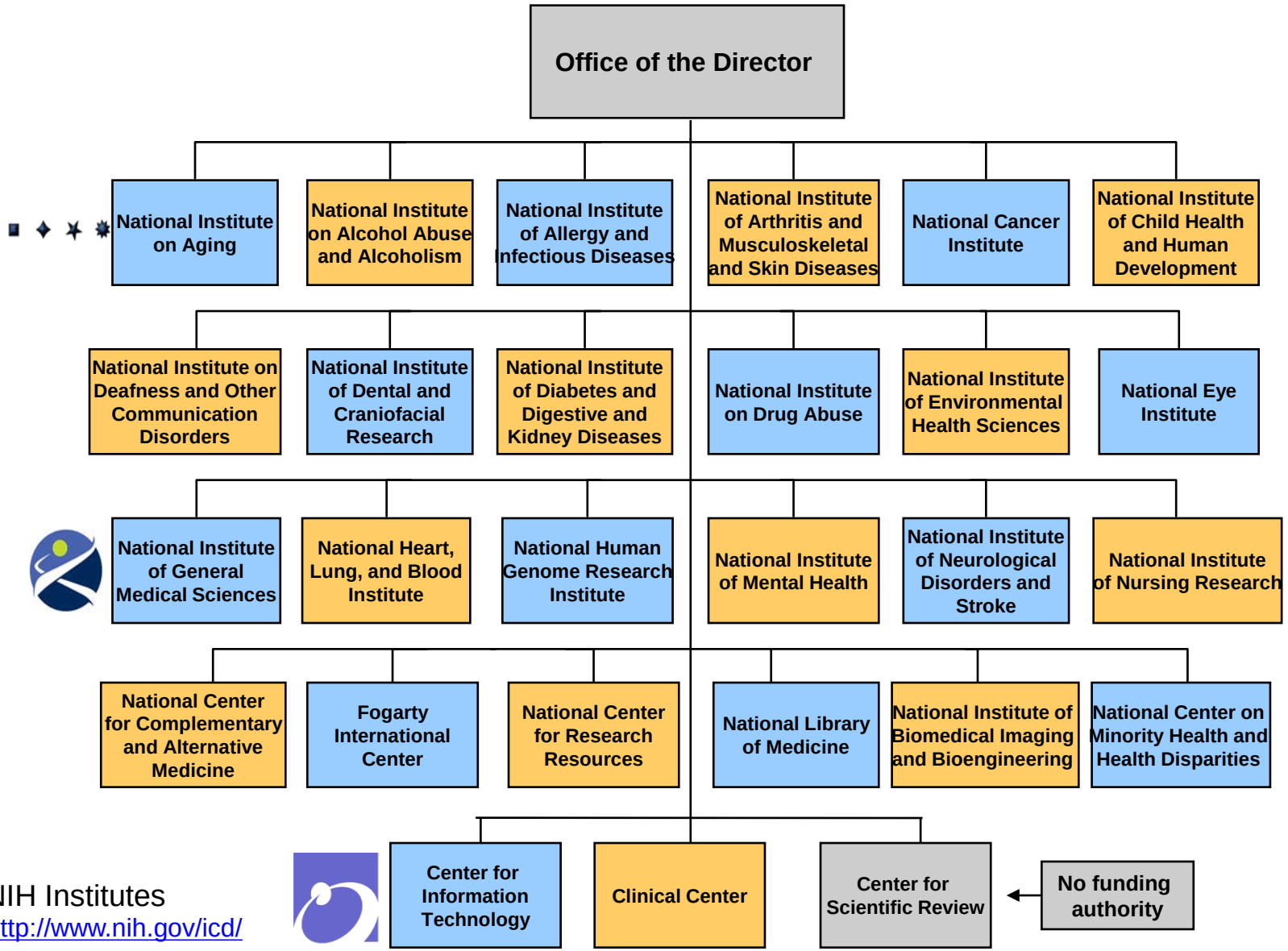
3. **Reviews** should be conducted **by outside experts** essentially without compensation.

4. Program **management and review** functions should be **separated**.

Surgeon General Thomas Parran, Jr.

Slide From Toni Scarpa, head NIH CSR

# NIH Structure



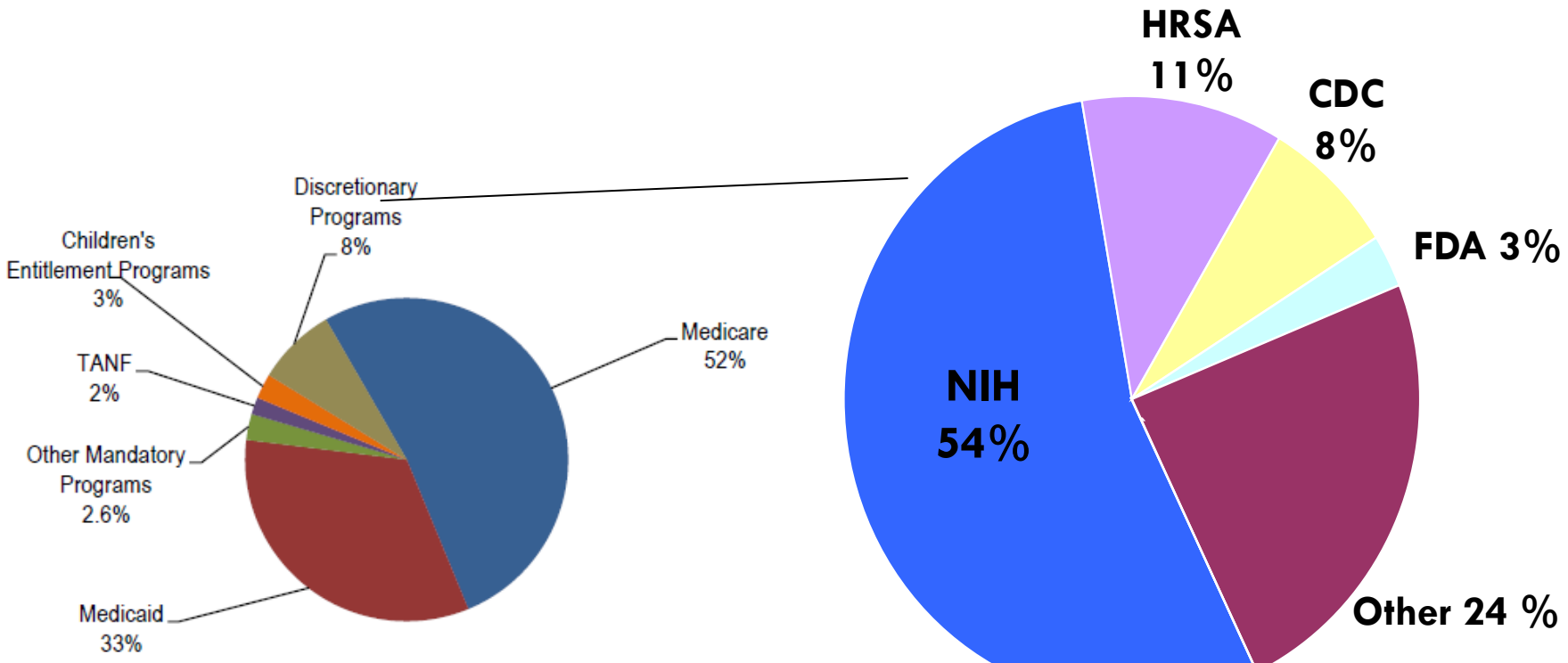

NIH Institutes
http://www.nih.gov/icd/

# Some NIH Funding Stats

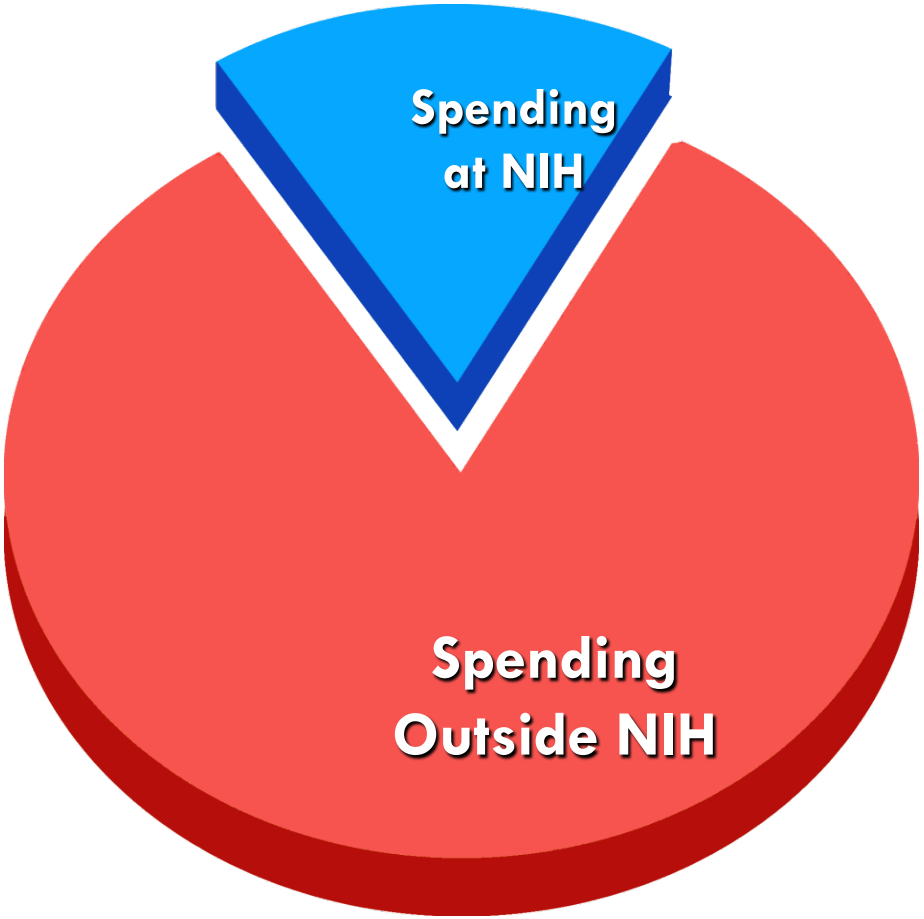
Getting the Facts

# Department of Health and Human Services

**Total Budget = $1010 Billion in 2015**

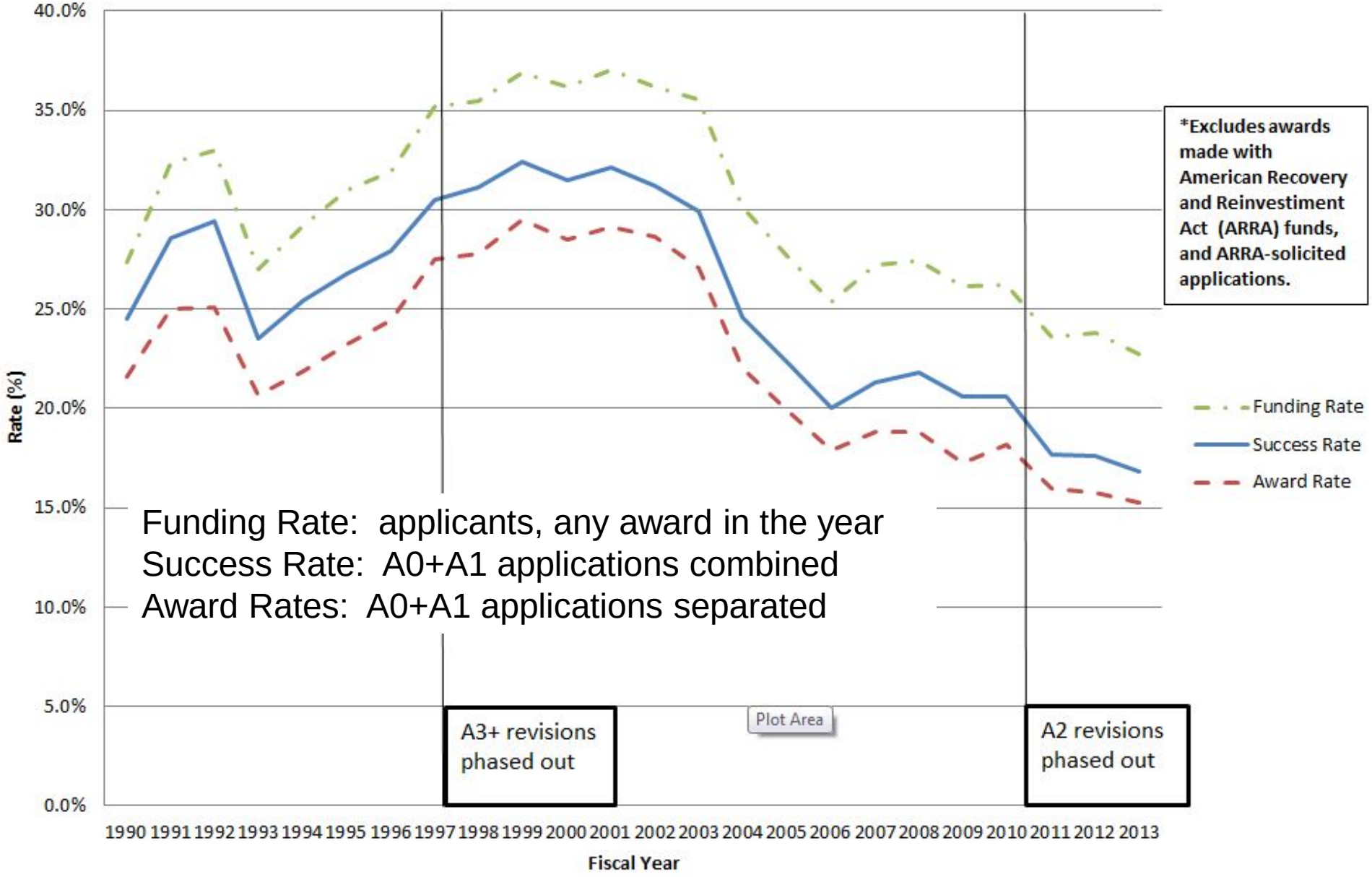


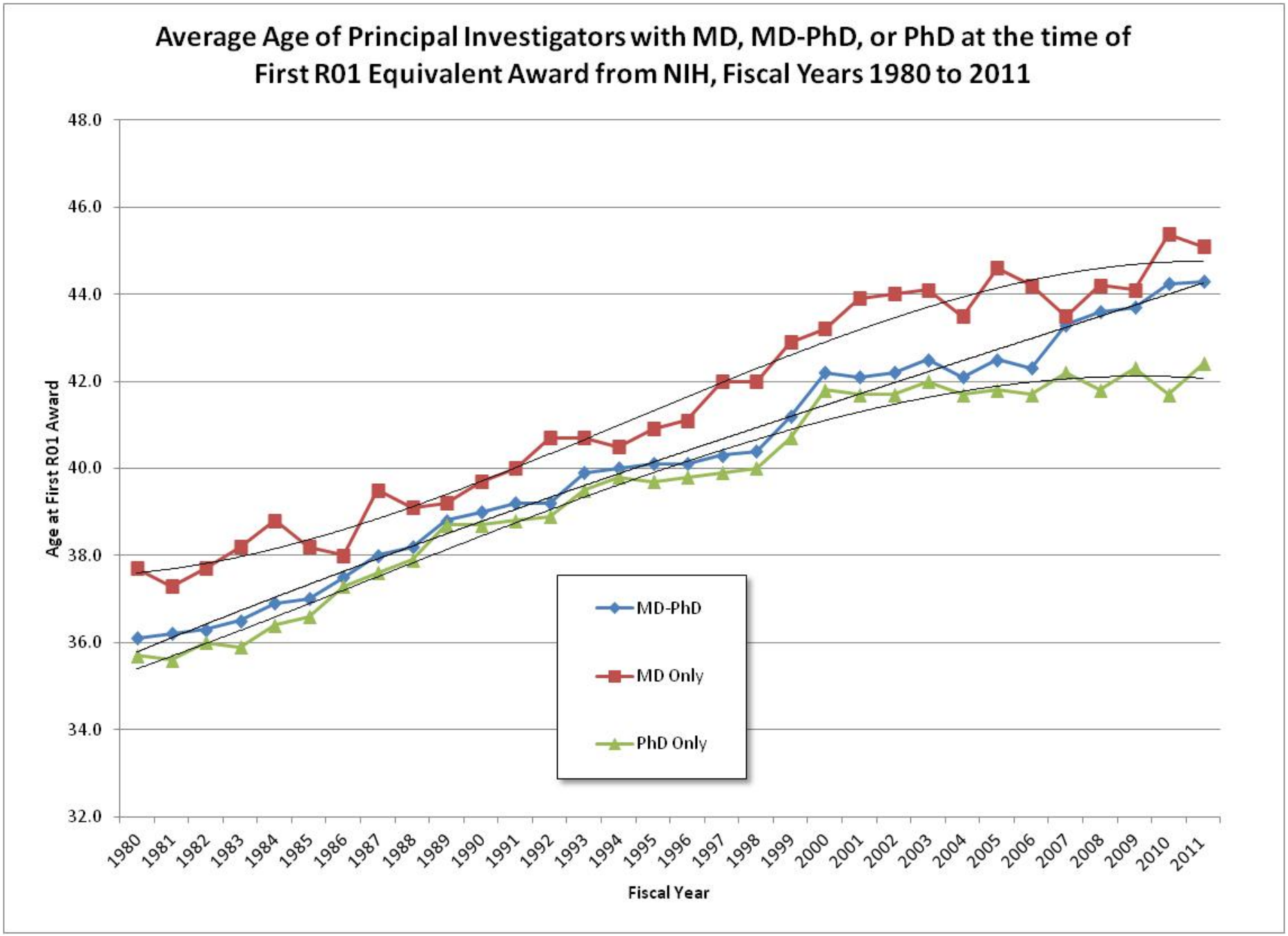
# FY 2015 NIH Budget -- $30.3 Billion




2003: *$27.1 billion*
2004: *$28.0 (+3.1%)*
2005: *$28.6 (+2.2%)*
2006: *$28.6 (-0.2%)*
2007: *$29.2 (+2.1%)*
2008: *$29.2 (0%)*
2009: *$30.4 (+4.1%)*
2010: *$30.8 (+1.4%)*
2011: *$30.7 (-0.3%)*
2012: *$30.6 (-0.3%)*
2013: *$29.2 (-4.5%,sequestration)*
2014: *$30.1*
2015: *$30.3*
2016: *$31.3 billion requested*

# Funding, Award and Success Rates* for Research Project Grants
## Fiscal Years 1990-2013




Average Age of Principal Investigators with MD, MD-PhD, or PhD at the time of First R01 Equivalent Award from NIH, Fiscal Years 1980 to 2011
Age at First R01 Award
48.0
46.0
44.0
42.0
40.0
38.0
36.0
34.0
32.0
1980
1981
1982
1983
1984
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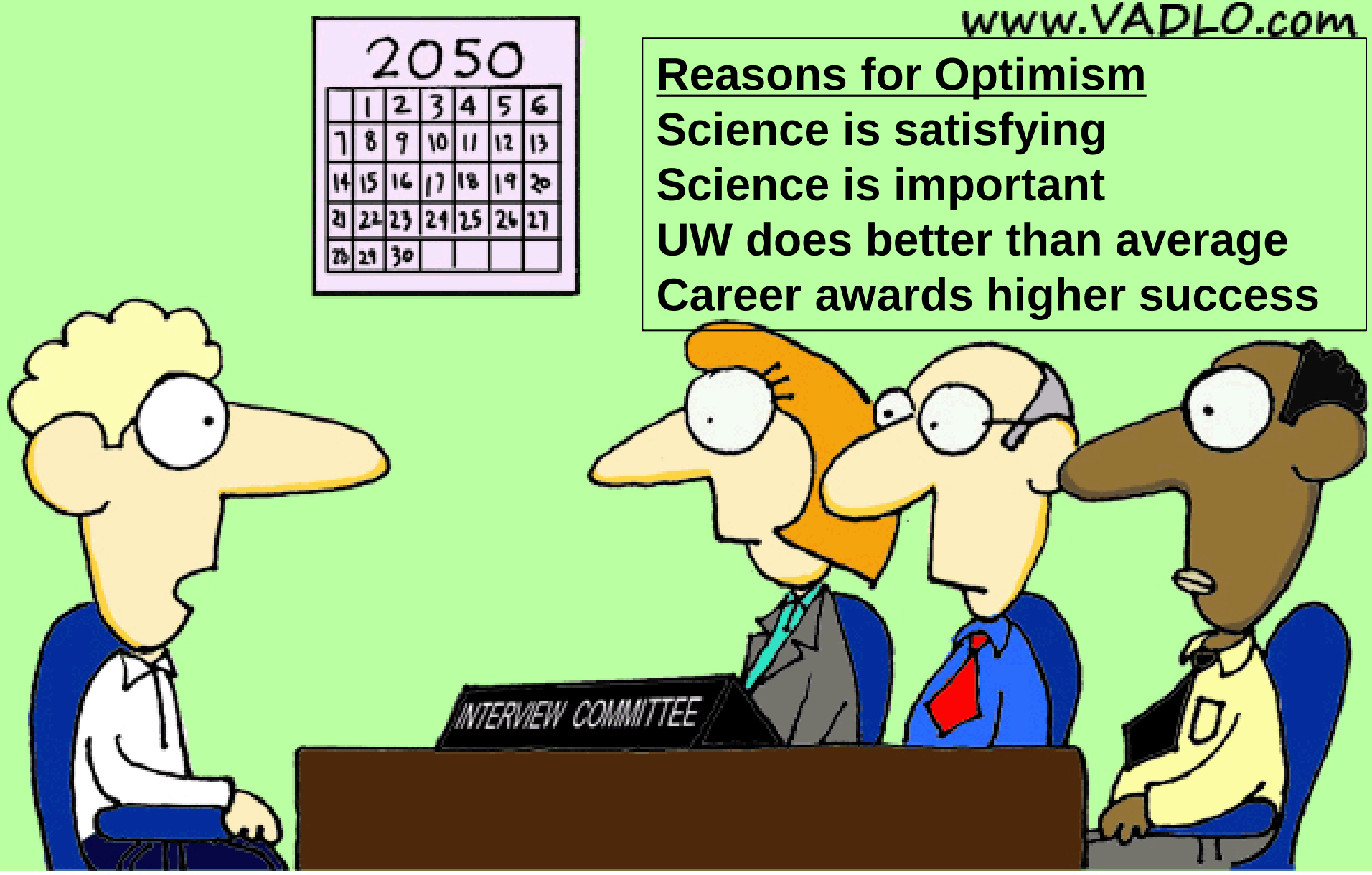
2008
2009
2010
2011
Fiscal Year
MD-PhD
MD Only
PhD Only




"...runs in our family. My father and grandfather are also working as postdocs."

# Good News:
# High Success Rates for Career Awards

| | | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2014 |
|---|---|---|---|---|---|---|---|---|---|
| **Success Rates** | | 36% | 35% | 31% | 31% | 35% | 38% | 36% | 30% |
| | K01 | 32% | 31% | 28% | 32% | 39% | 36% | 40% | % |
| | K02 | 47% | 38% | 35% | 42% | 38% | 36% | 29% | % |
| | K07 | 20% | 22% | 24% | 26% | 34% | 39% | 22% | % |
| | K08 | 40% | 39% | 34% | 36% | 44% | 47% | 44% | 40% |
| | K12 | 31% | 28% | 34% | 45% | 53% | 52% | 49% | % |
| | K22 | 32% | 29% | 29% | 27% | 23% | 26% | 25% | % |
| | K23 | 36% | 34% | 27% | 33% | 38% | 44% | 38% | 38% |
| | K24 | 42% | 51% | 44% | 47% | 50% | 47% | 61% | % |
| | K25 | 30% | 33% | 31% | 35% | 48% | 22% | 30% | % |
| | K99 | | | 100% | 20% | 23% | 29% | 25% | 22% |
| | Other Ks | 49% | 60% | 48% | 49% | 67% | 66% | 47% | % |

# Top NIH Funded Institutions 2013

The Good News: UW Has Flourished

| ORGANIZATION | CITY | STATE | AWARDS | FUNDING |
|---|---|---|---|---|
| JOHNS HOPKINS UNIVERSITY | BALTIMORE | MD | 1190 | $573,828,199 |
| UNIVERSITY OF CALIFORNIA, SAN FRANCISCO | SAN FRANCISCO | CA | 1189 | $537,261,995 |
| UNIVERSITY OF PENNSYLVANIA | PHILADELPHIA | PA | 1083 | $478,450,858 |
| UNIVERSITY OF WASHINGTON | SEATTLE | WA | 926 | $423,942,137 |
| UNIVERSITY OF PITTSBURGH | PITTSBURGH | PA | 925 | $419,326,750 |
| UNIVERSITY OF MICHIGAN | ANN ARBOR | MI | 986 | $412,757,614 |
| UNIV OF NORTH CAROLINA CHAPEL HILL | CHAPEL HILL | NC | 901 | $392,806,930 |
| STANFORD UNIVERSITY | STANFORD | CA | 849 | $384,340,065 |
| UNIVERSITY OF CALIFORNIA SAN DIEGO | LA JOLLA | CA | 848 | $382,491,697 |

# Source of Research Funds at UW

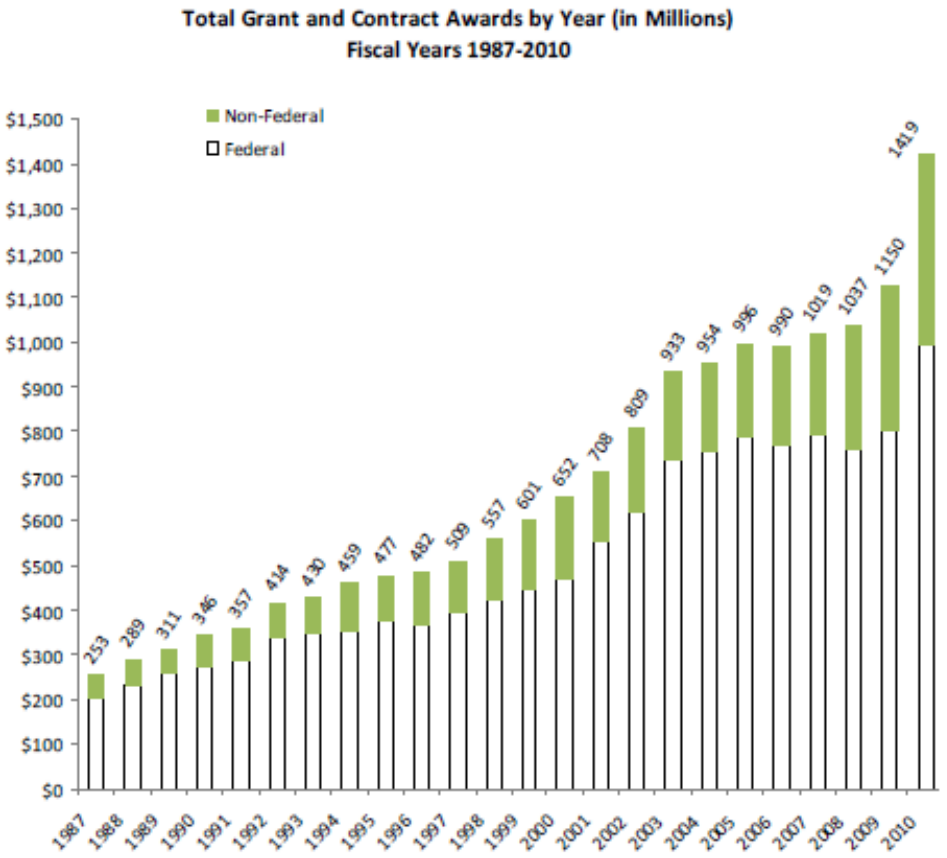
*~2/3 of Research Funds at UW Are Federal*

- Federal sources are gold standard of UW funding
- Essential for advancement and promotion
  - Your salary support
- Most important:

Indirect Costs:

Main UW Campus: $1 = $0.54

SLU Campus: $1 = $0.74



# Scenario—Who to Ask

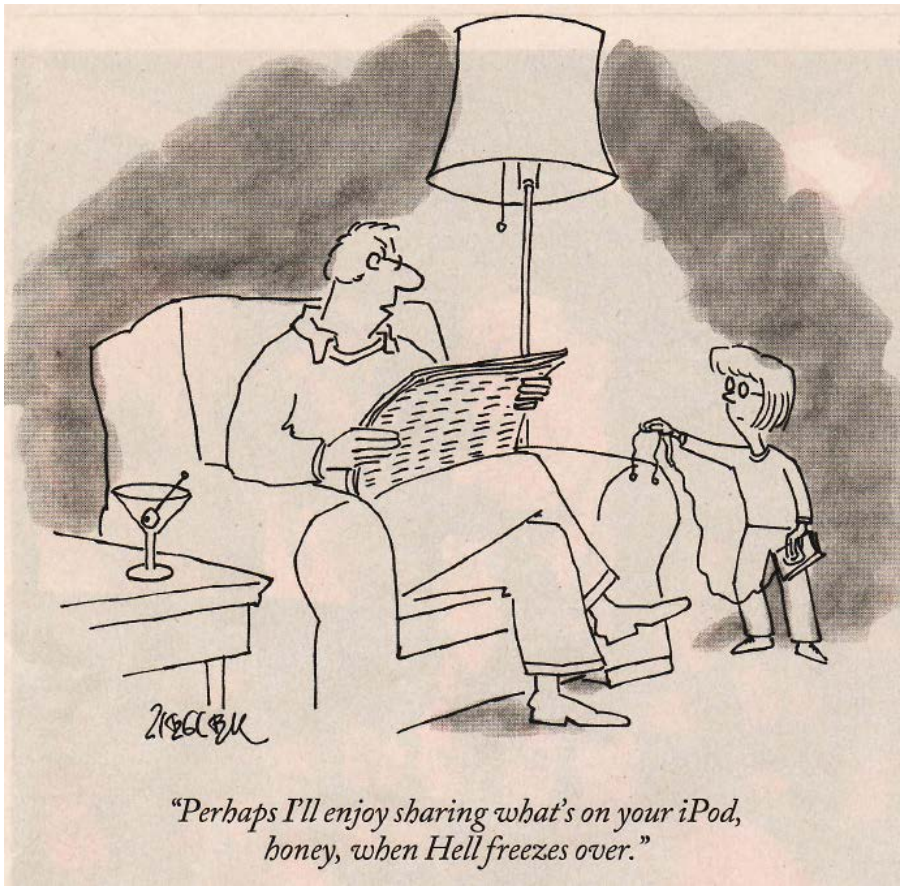
You are ready to apply for a grant and have many questions. Where do you get information? What do you apply for?

1. Grants Management Specialist
2. Study Section Chairperson
3. NIH Scientific Review Officer (SRO)
4. NIH Program Officer (PO)

# The SRO and the Program Officer

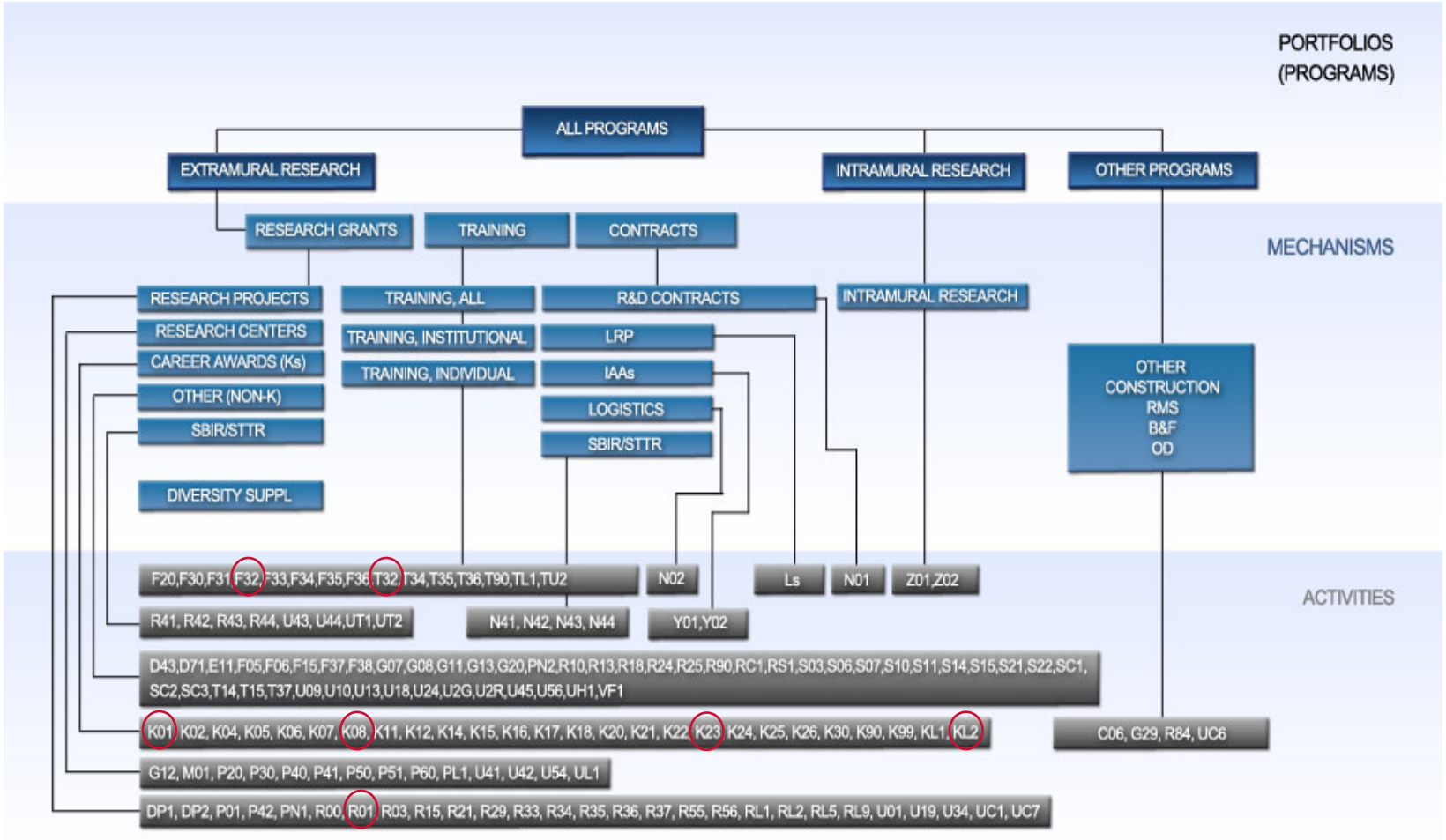
- **Scientific Review Officer (SRO)**
  - 240 SROs in CSR
  - Legal Responsibility for Study Section Mtg
  - Selection of Study Section Members
  - Assignment of Applications
  - Follow the law, the rules and the regulations
  - Assisted by Grants Management Specialist
- **Program Officer**
  - Role before and after review
  - Key “translator” of summary statements for investigator
  - Responsible for programmatic, scientific, and/or technical aspects of a grant.

# Solicit Advice Broadly …

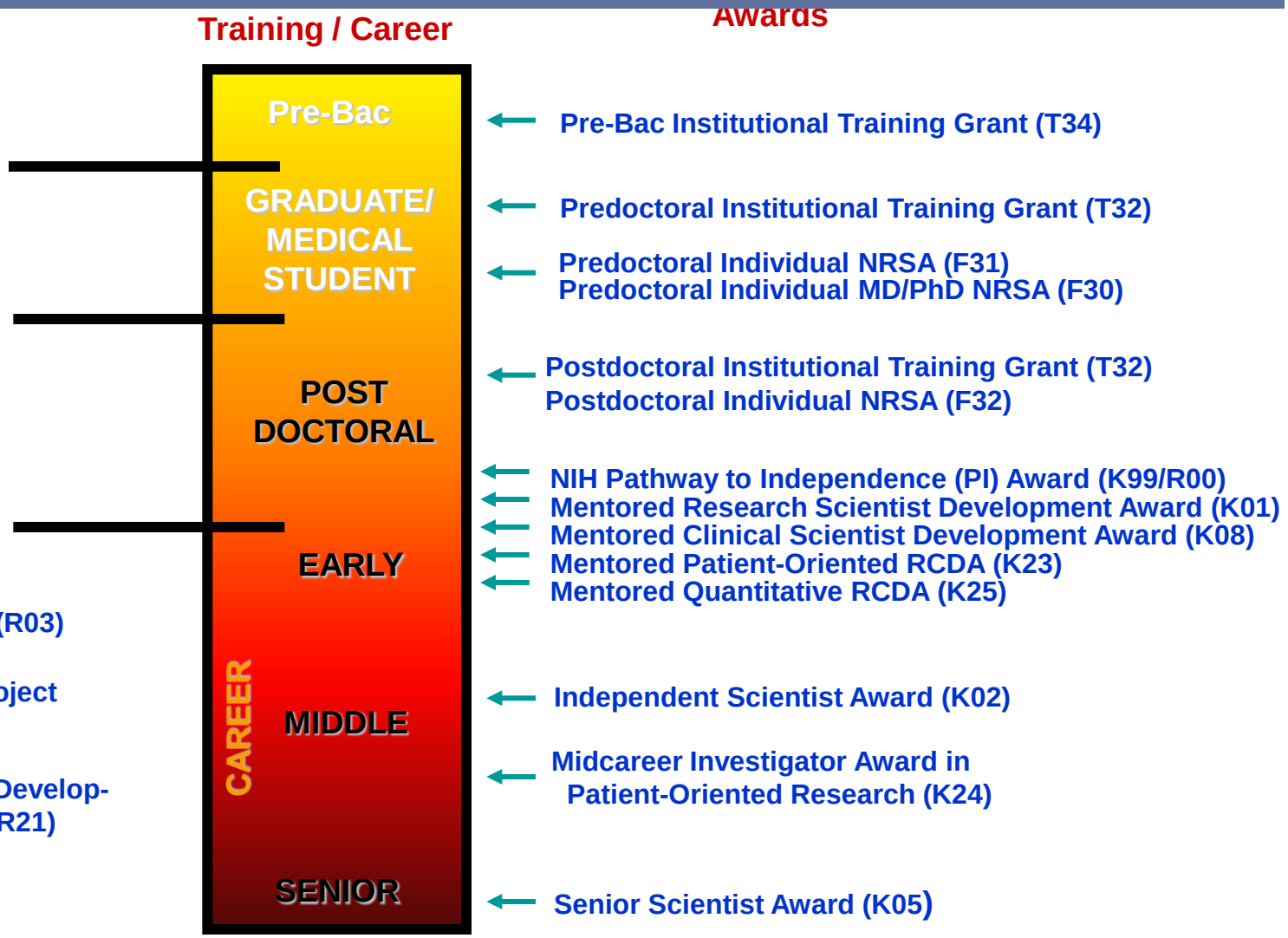



Mentor
Fellows
Post-docs
Colleagues
NIH

# NIH Award Mechanisms



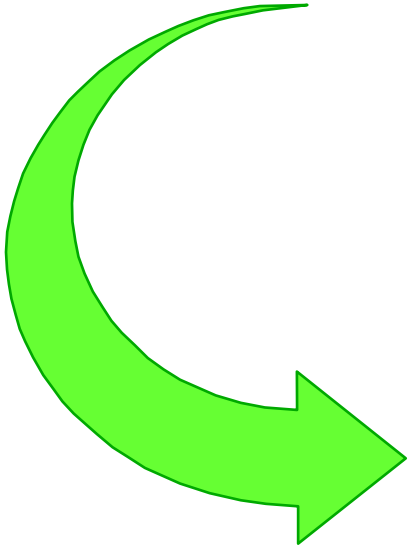
# Training and Career Timetable



# Behind the Scenes at an NIH Study Section

# Dual Review System for Grant Applications

**First Level of Review= CSR**
**Scientific Review Group (SRG)**



- **Second Level of Review**
- **NIH Institute/Center Council**

## NIH owns review process

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

## Study section owns the science review

## Ownership of application:

- - CSR from receipt to posting of Critiques
- - Institute/Center after Critique posting

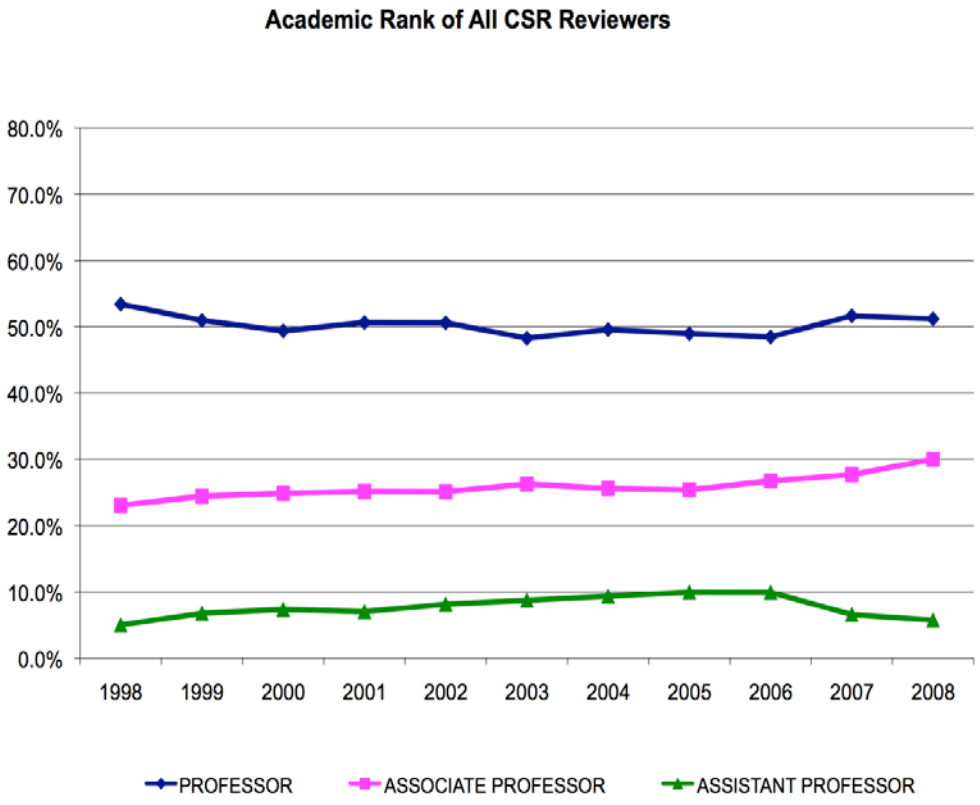
# Evolution of Study Sections

**1946**
**The First NIH Study Section**

**An NIH Study Section Today**

# Study Sections

- Organized into IRGs (Integrative Review Groups)
- Headed by an SRO (Scientific Review Officer)
- 12-25 members, essentially all from academia
  - About ½ are ad hoc reviewers
- 60-100+ applications per meeting
  - ~12 per member
  - 3 reviewers per applications
- Information from CSR web site: http://cms.csr.nih.gov/
  - Study section scope
  - Roster of reviewers
  - Policies
  - Schedules
- Study sections are advisory - they do not fund applications.



# Review Process - Before the Meeting

- Scores and critiques are uploaded 1 week before study section
- Each criterion is given a score: 1, 2, 3…9 (best to really bad)
  - These are not discussed at the Study Section
  - But they are included in the Summary Statement you will get
- Each reviewer gives an overall Impact Score
  - Impact Score is not the mean of the criteria scores
  - Impact score is key and the only score discussed
- Initial scores and critiques become available to all committee members
- Applications are ranked in order of initial mean Impact Scores
- Lower 40-60% are not discussed (Impact Score of 4.5 – 5.0 and above)
  - Any “triaged” application can be resurrected at the meeting for discussion for any reason
  - Applicants receive the critiques and individual criteria scores
  - Impact Score is not given

# Peer Review Information

- Overall Impact : Provide an overall impact score to reflect your assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable).
- Scored Review Criteria: Determination of scientific merit: Impact scores
  1. Significance
  2. Investigator(s)
  3. Innovation
  4. Approach
  5. Environment
- Additional Review Criteria : can impact scores
  1. Protection for human subjects (and inclusions)
  2. Vertebrate animals
  3. Biohazards
  4. Resubmission, Renewal, Revision
- Additional Review Considerations: do not impact scores
  - Select Agents
  - Resource sharing plan: Data sharing, model organisms, & GWAS
  - Budget
- Scoring scale of 1 – 9 (Best to worst)
- Budget: does not impact scores. Discussed after the final vote

# Scored Review Criteria

## Individual Training F-series Grants

- Overall Impact

Review Criteria

- Candidate
- Sponsor, Collaborators, Consultants
- Research Training Plan
- Training Potential
- Institutional Environment & Commitment to Training

## Career Development K-series Grants

- Overall Impact

Review Criteria

- Candidate
- Career development plan
  Career goals and objectives
  Plan to provide mentoring
- Research Plan
- Mentor(s), consultants, collaborators
- Environment & Institutional commitment

## Investigator Initiated R-series Grants

- Overall Impact

*Review Criteria*

- Significance
- Approach
- Innovation
- Investigator
- Environment

# Scoring System

- Criterion Score
  - Whole numbers: 1-9
  - 1 (exceptional); 9 (um, well let's just hope you never get a 9)
  - Given by reviewers but not discussed at study section
  - Provided in Summary Statement of all applications (discussed and not discussed)
- Overall Impact Score
  - Whole numbers (at first): 1-9
  - Not the mean of the criteria scores
  - Different criteria are weighted by each reviewer
  - Each review recommends a score
  - All committee members score within the range
  - Can vote outside the range, but must state that you are doing so
- Final Impact Score
  - Mean of all scores x 10
  - 10 – 90
  - Percentiled against similar applications across 3 meetings (not so for F's and K's)
  - Unknown to the committee (except the chair)
- Payline
  - Varies among institutes
  - http://www.aecom.yu.edu/ogs/NIHInfo/paylines.htm

**Adjectives Used**

| | |
|---|---|
| 1 | Exceptional |
| 2 | Outstanding |
| 3 | Excellent |
| 4 | Very Good |
| 5 | Good |
| 6 | Satisfactory |
| 7 | Fair |
| 8 | Marginal |
| 9 | Poor |

# Impact Score

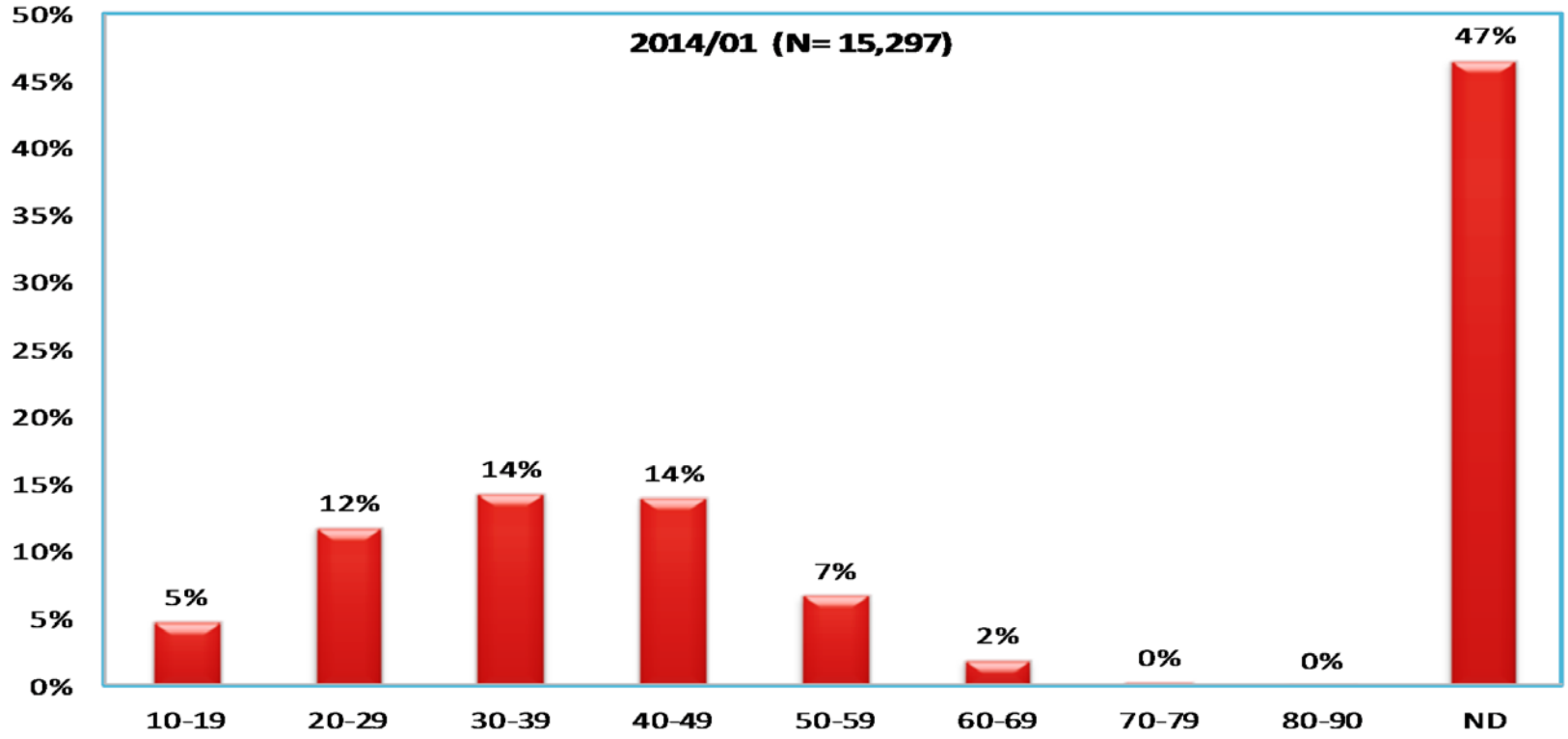
| Impact | Score | Descriptor | Strengths/Weaknesses |
|---|---|---|---|
| High Impact | 1 | Exceptional | Strengths |
| | 2 | Outstanding | |
| | 3 | Excellent | |
| Moderate Impact | 4 | Very Good | |
| | 5 | Good | |
| | 6 | Satisfactory | |
| Low Impact | 7 | Fair | |
| | 8 | Marginal | |
| | 9 | Poor | Weaknesses |

# Criteria Scores

| Score | Descriptor | Additional Guidance on Strengths/Weaknesses |
|---|---|---|
| 1 | Exceptional | Exceptionally strong with essentially no weaknesses |
| 2 | Outstanding | Extremely strong with negligible weaknesses |
| 3 | Excellent | Very strong with only some minor weaknesses |
| 4 | Very Good | Strong but with numerous minor weaknesses |
| 5 | Good | Strong but with at least one moderate weakness |
| 6 | Satisfactory | Some strengths but also some moderate weaknesses |
| 7 | Fair | Some strengths but with at least one major weakness |
| 8 | Marginal | A few strengths and a few major weaknesses |
| 9 | Poor | Very few strengths and numerous major weaknesses |

Minor Weakness: An easily addressable weakness that does not substantially lessen impact
Moderate Weakness: A weakness that lessens impact
Major Weakness: A weakness that severely limits impact

# CSR All 2014-01 Histogram

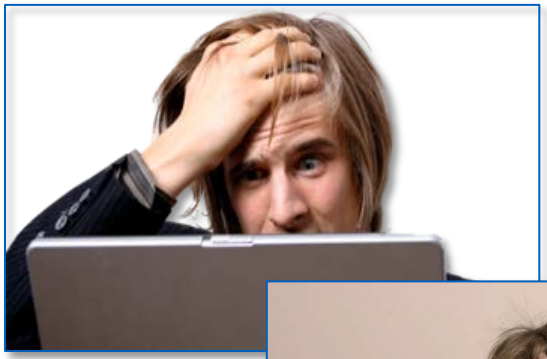



1. Shows recent scoring pattern of ~15,000 applications
2. Score is well spread over a range of ~10 - 69
3. In a regular study section panel, ~5% of applications get a score of 10-20 and about 2% perform poorly.

# Where and When Do Reviewers Review Grant Applications?

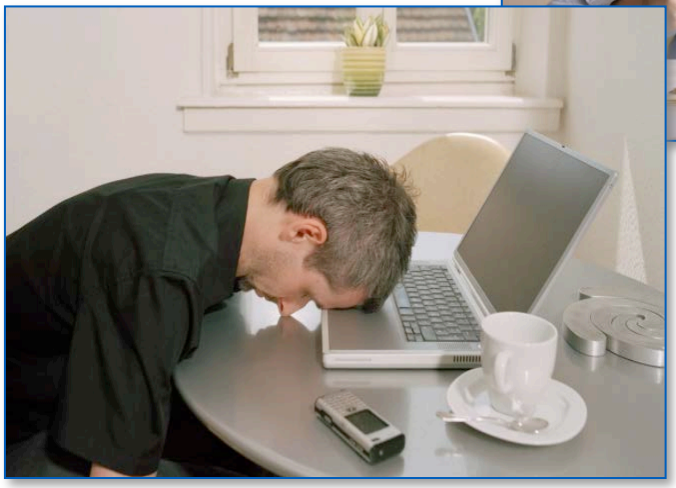
- At home
- On a plane (likely no internet)
- At the last minute - and thus a bunch in one sitting
- Hence, reviewers can be stressed, anxious, & not terribly sympathetic
- They may lose interest

**Don't let the reviewer become…**



**Baffled,**

**Bitter,**



**or Bored**

- *Do not make the reviewer think!*
- *Do not make the reviewer read papers or go to the internet*
- *Do not tick off the reviewers!*

Slide from Bill Parks

# The Review Process - at the Meeting

- Begin at 8 am EST (i.e., 5 am PST)
- Cramped room full of lap tops and several jet-lagged reviewers
- Review Grants in order - best to less best
- 15-20 min per application (shorter is best)
- Go to 6-7 pm
- Bar, eat, bar, sleep
- Repeat next day

# The Review Process - at the Meeting

*What happens?*

- Application is announced and conflicts identified
- Chair asks the 3 reviewers to state their scores
- Primary reviewer discusses strengths and weaknesses using the scored criteria as a guide (but without stating criterion scores)
- Other reviewers concur or discuss differences
- Additional Review Criteria: Animals, Human Subjects, Resubmission
- Discussion opens to the committee
- Reviewers restate their scores (e.g., 2-4-5, 3-3-3)
- A range is established (e.g., 2-5, 3-3)
- Chair asks if anyone plans to vote outside of the range
- Committee posts scores online
- Additional Review Considerations: Budget, Resource Sharing, Bioethics training
- Repeat with the next application in order

# Summary Statement

- Face Page
- Summary of Discussion
- Description (abstract you wrote)
- Overall Impact and Scored Criteria
- Addition Review Criteria
  - Protection of Human Subjects
  - Inclusion of Women, Minorities, and Children
  - Vertebrate Animals
  - Biohazards
  - Resubmission
- Additional Review Considerations
  - Responsible Conduct of Research
  - Budget
  - Foreign Training
  - Resource Sharing Plan
- Additional Comments to the Applicant
  - Excess text in the wrong place
  - Advice for resubmission

Individual Critiques

# Vagaries of Peer Review

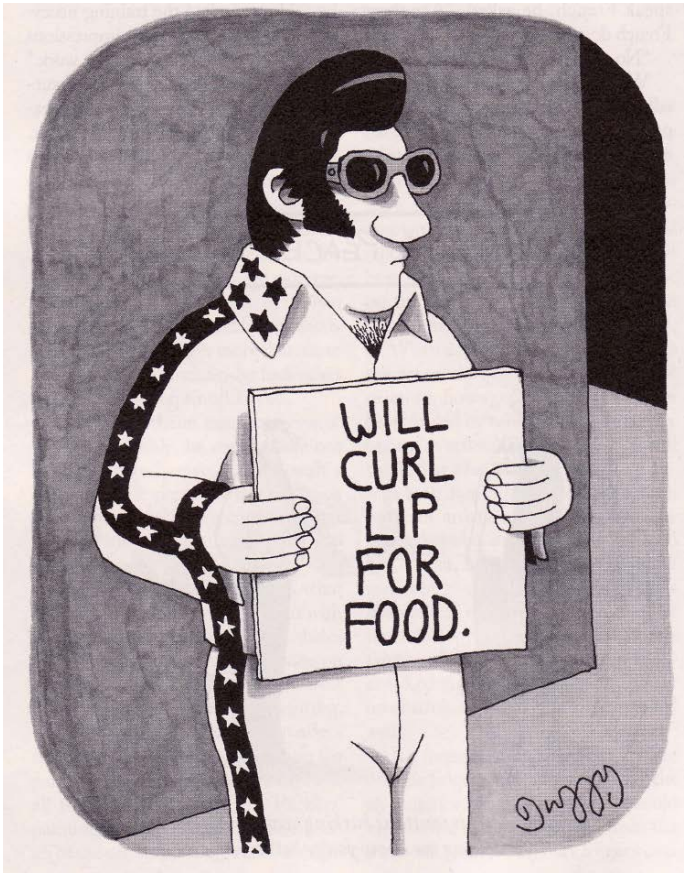
- Reviewers are humans; humans err
- Assigned reviewers have the most influence on scoring
- A passionate reviewer (pro or con) can influence the group
- Any committee member can vote outside of the “range”
- Final Impact Score is usually (~85% of the time) close to the initial impact score
  - Scores change >1 point on only 15% of grants
  - Rarely for ESI applications (less than 1%)

Good video of a mock Study Section
http://www.youtube.com/watch?v=fBDxI6l4dOA

# Some Top Reasons Why Grants Don't Get Funded

- Lack of new or original ideas.
- Diffuse, superficial, or unfocused research plan.
- Lack of knowledge of published, relevant work.
- Lack of preliminary data and/or experience with essential methodologies.
- Uncertainty concerning future directions (where will it lead?).
- Questionable reasoning in experimental approach.
- Absence of a sound hypothesis and clear scientific rationale.
- Unrealistically large amount of work.
- Poor training potential.
- Poor productivity.
- Mentor is not qualified, poorly funded, and/or not productive.

# If All Else Fails ….



# Additional Information

The NIH has put together a series of podcasts in their “All About Grants” webpage (see link below). It looks like a fantastic resource, especially for early stage investigators.

General topics include:
Getting to know NIH and the Grants Process
Preparing a Successful Grant Application
Advise for New and Early Career Scientists
Submitting your Application
How NIH Grants are Reviewed
Life as an NIH Grantee (Post-Award Activities and Requirements)

http://grants.nih.gov/podcasts/All_About_Grants/index.htm

# Website References

NIH
Grants Page: http://grants.nih.gov/grants/oer.htm

NRSA (T+F Grants): http://grants.nih.gov/training/nrsa.htm

K Career Development Awards:
http://grants.nih.gov/training/careerdevelopmentawards.htm

# Additional Information

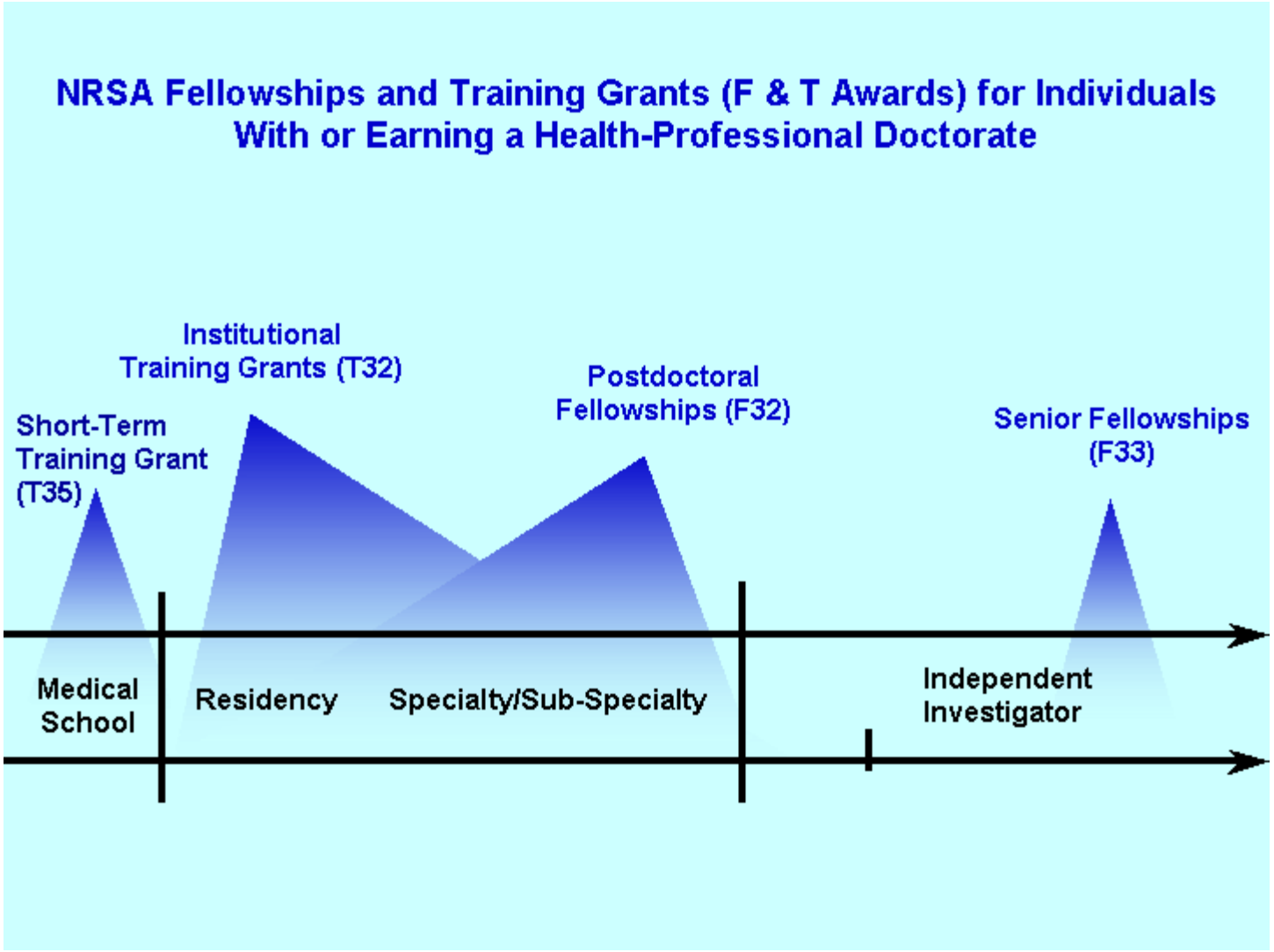
# T & F Grants

- Institutional Awards:  T32
  - Institution, not the individual, applies for the award
  - **Not available at all schools, departments, divisions**

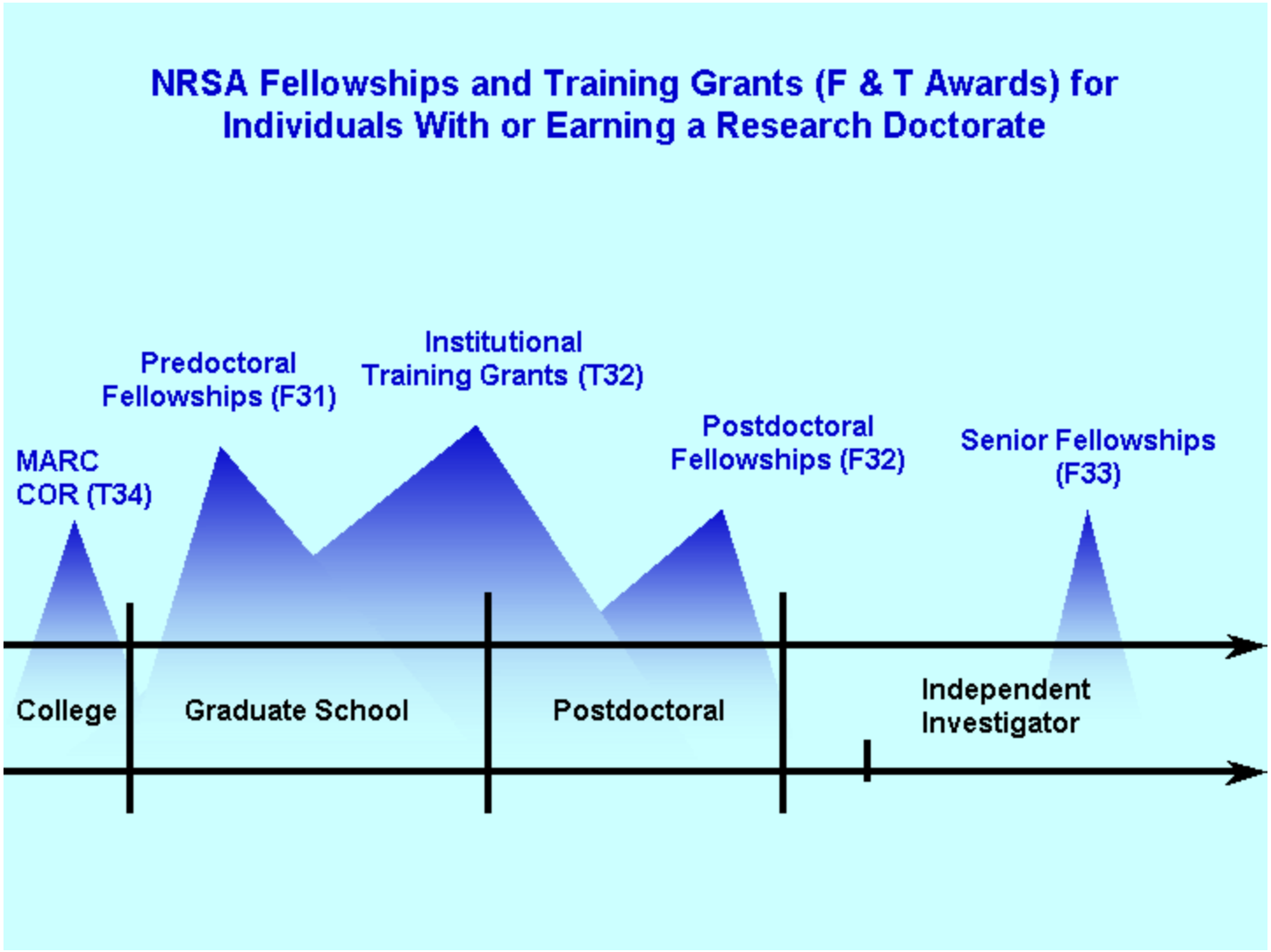
- Individual Awards:  F32
  - Mentored
  - Independent—can interact with other NIH Awards
  - Depending on the award, all doctorates or restricted to clinical doctorates
  - NIH support varies by Institute

**TOTAL YEARS of F and T NIH Grant Support=3 YEARS**

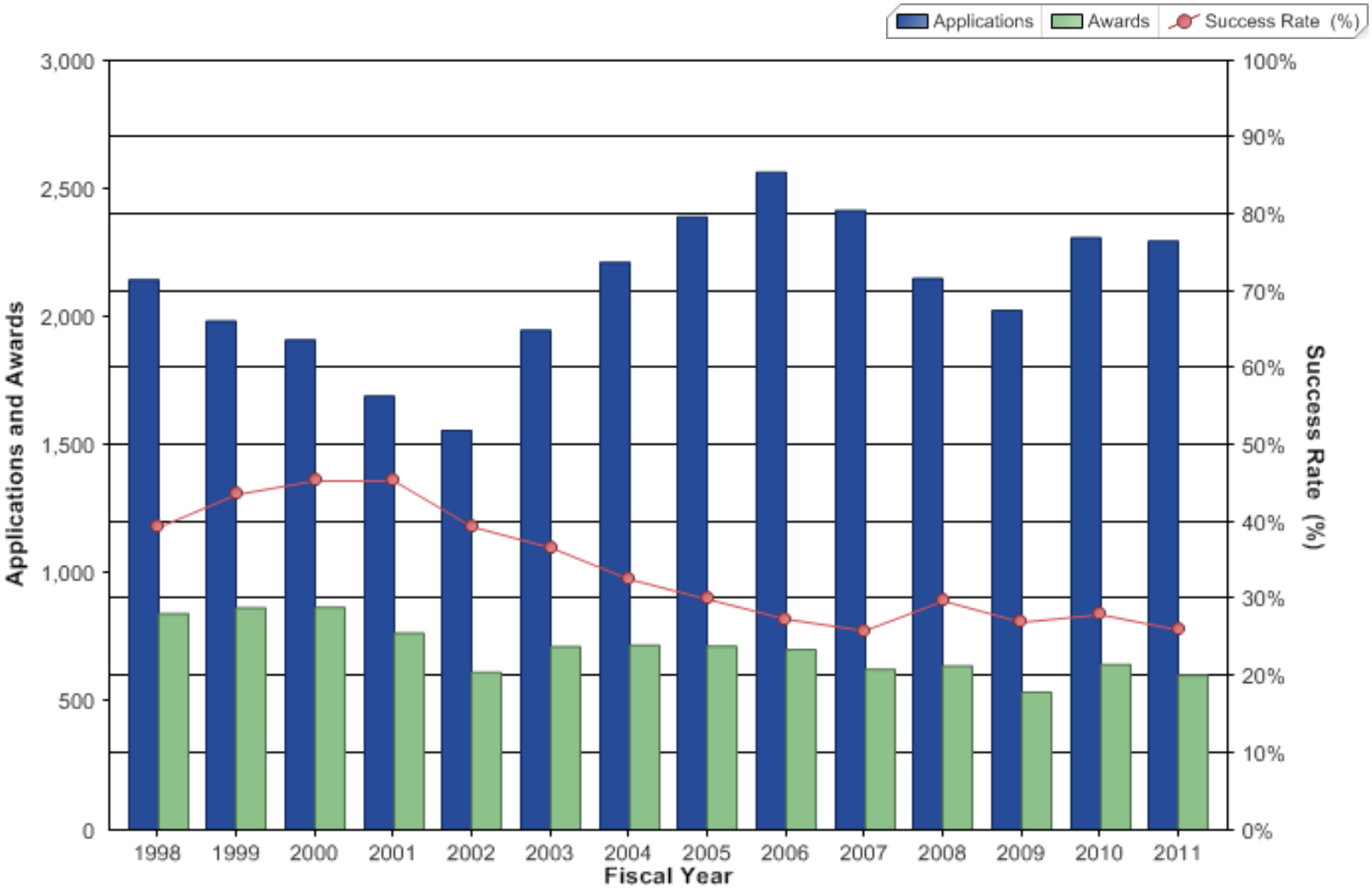
# Training Grant Awards—Clinical Track



# Training Grant Awards—PhD Track

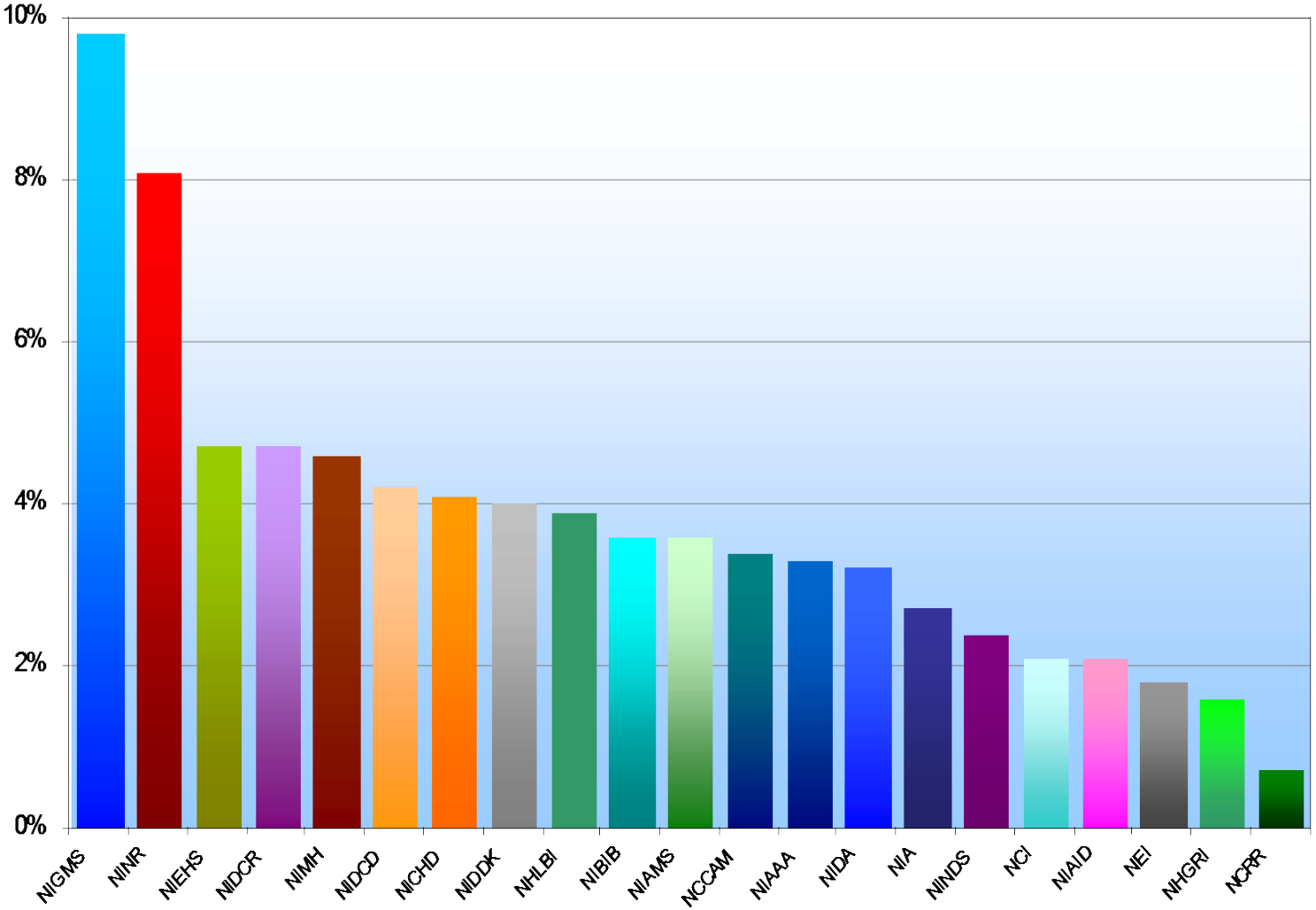


# F32 NRSA Success Rates




Kirschstein-NRSA post-doctoral fellowships (F32s)
Competing applications, awards, and success rates

# NRSA Support Varies by Institute




NRSAs by Institutes - 2007

# New Investigator

- A Principal Investigator (PI) who has not yet competed successfully for a substantial, competing NIH research grant (R01 or 'higher') is considered a New Investigator
- http://grants1.nih.gov/grants/new_investigators/resources.htm

# Early Stage Investigator (ESI)

- An individual who is classified as a New Investigator and is within 10 years of completing his/her terminal research degree or is within 10 years of completing medical residency (or the equivalent)

# Extension of ESI Eligibility

- The 10-year period may be extended to accommodate special circumstances (e.g. medical concerns, disability, pressing family care responsibilities, or active military duty service)

# What Affects New Investigator Status?

- PI of an R03 or R21? *No*
- PI of an NIH contract? *No*
- PI of a grant with another Federal agency? No
- PI of an SBIR/STTR? *No*
- PI of a U01, specifically for a foreign investigator?

  *Receipt of U01 removes NI status.*
- Inheriting an R01 from a PI who moved away or died? *No*

# Other Grant Sources To Consider

**NIH Loan Repayment Program**

For individuals with clinical doctorate degrees working in **specified areas of biomedical science,** predominantly **patient-oriented research**

**Examples of Sources of Non-Federal Grants**

American Hearth Association

Infectious Diseases Society of America

Cystic Fibrosis Foundation

Parker B Francis Foundation