Challenges and Opportunities in Peer Review

A Vision for Ensuring Its Strategic National Value

Toni Scarpa
a.scarpa@csuohio.edu
440 891 6022

Cleveland State University
Cleveland, OH
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The Strategic National Importance of Peer Review

NIH and Peer Review
NIH Center for Scientific Review
The Drivers for Change
Enhancing Peer Review
The Strategic National Importance of Peer Review

30 Years of Medical Innovation

- MRI and CT Imaging
- ACE inhibitors
- Angioplasty
- Stains
- Mammography
- Coronary Interventions
- H inhibitors and H2 Blockers
- Antidepressants
- Cataract and Lens Replacement
- Ultrasound Imaging
- Asthma Treatment

- Cardiac Enzymes
- Fluoroquinolones
- Hypoglycemic Agents
- HIV Testing and Intervention
- Tamoxifen
- PSA
- H. Pylori Test and Treatment
- Bone Densitometry
- Cephalosporins
- Calcium Blockers

Facts and Sec, Health Affairs, 20, 30-42

NIH Support to Scientists Who Later Received Nobel Prizes in Physiology/Medicine or Chemistry

Why Has The U.S. Biomedical-Behavioral Research Been So Successful?

It is not the money but the way it is spent

Nobel Prizes and Major Discoveries

Global Federal Expenditure for Biomedical Research in Developed Countries

USA 91%

91% 9%

Department Health and Human Services

Organization

Ministry of university science/research/education

Goal

Promote biomedical research

Provide employment for scientists

Promote cures

Reengineer medicine

How funds are allocated

Large entitlement to universities, research centers

Small fraction through peer review to researchers

100% through peer review to researchers

Others

Departments of university science/research/education

Departments of university science/research/education
The Rules and the Results of the Process

• 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

Funding Longevity of NIH Investigators

How a Mosquito Helped Creating the NIH (and the USA)

Yellow Fever and the Decline of French America

Memphis: Death and Exodus

Louisiana Purchase 1803
1879

- A $30,000 bid (RFA) from the US Army for Universities.
- 1st peer-reviewed applications for research.

Carlos Finley and Walter Read

Penicillin and World War II

1940

- President Roosevelt set up the National Defense Research Committee.
- Awarded contracts for rapid production projects.
- Identified 700 universities for future contracts.

1942

- Medical Research funding grew from $2.3 million to $7.5 million, rating applications with an "A", "B", or "C".
- 21 penicillin production plants (led to a 97% survival rate for wounded soldiers.)

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 National Institutes of Health

Department of Health and Human Services

Total = $592 Billion

- Medicare
  - 58%
- Medicaid
  - 33%
- NIH
  - 54%
- Other 24%
- CDC
  - 8%
- FDA 3%
- Discretionary Programs
  - 11%
FY 2012 NIH Budget

Distribution of Funding

NIH Center For Scientific Review

Types of NIH Grants

• Research Project Grant
• Small Business Grants
• Training and Career Development Grants
• Exploratory/Development Grants
• Shared Instrumentation Grants
• Resource Grants

The Operating Principles of NIH Peer Review

NIH has ownership of the process

• The Scientific Review Officer, a full time federal employee, nomintates the review panel, assigns applications and is responsible for the meeting

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

• Is composed by experienced scientists in the field.
• Hundreds of study sections reviewing different biomedical behavioral science
This is CSR

The Drivers for Change

1st Driver: The NIH Budget

2nd Driver: Number of Applications

3rd Driver: Reviewer’s Load

4th Driver: CSR Budget
Annual Savings in Reviewers’ Expense Budget

- Sending application electronically: $3.8 million
- Non-refundable tickets with one possible change: $15 million
- 3,000 fewer reviewers: $3 million
- 15% reviews using electronic platforms: $5 million
- One meeting a year on the West Coast: $1.8 million

5th Driver: The World Is Changing

- The way research is done has changed
- The diseases of Americans have changed

The Land of the Free, The Home of the Fries

Enhancing Peer Review

Major Complaints About NIH Peer Review

- The process was too slow
- There were not enough senior/experienced reviewers
- The process favored predictable research instead of significant, innovative, or transformative research
- The time and effort required to write and review were a heavy burden on applicants and reviewers

Enhancing Peer Review: The Overall Goal

1. Modernizing the Process
2. Realigning Study Sections, Divisions, IRG
3. Investing in the Future: Young Investigators
4. Funding the Most Promising Research Earlier
5. Focusing More on Impact and Significance
6. Attracting and Maintaining the Best Reviewers
7. Others
NIH Review Changes
The Process

- Input from the community
- Open Houses
- PRAC (Peer Review Advisory Committee)
- NIH Intramural and NIH IC Directors
- Department Health and Human Services
- OMB and White House

Enhancing Peer Review

1. Modernizing the Process
2. Realigning Study Sections, CSR Divisions and IRGs
3. Investing in the Future: Young Investigators
4. Reviewing Expeditiously
5. Focusing More on Impact and Significance
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7. Others

1: Processing Applications

- CSR: July 1, 2005
- CSR: February 1, 2007

1. One Review Platform for 63 years
The First NIH Study Section 60 years later

1946 2005

1. Advancing Additional Review Platforms

- Electronic Reviews
  - Video Assisted Meeting
  - Internet Assisted Meeting
- Editorial Board Review
  - Complex Science
  - Small Business
  - Transformative R01
  - ARRA, IRS, FDA applications
1. The First Telepresence Study Section

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2. CSR Organization

Division | Integrated Review Groups | Scientific Review Officers
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2. Redesign Study Sections

Positional Map of Membranes Biology and Protein Processing

2. Redesign Study Sections

Positional Map of Musculoskeletal Tissue Engineering

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3. Projection of Age Distribution of NIH RPG Investigators: 2020

3. Early Stage Career Investigators

Definition of New Investigator:
- Not previously competed successfully as PD/PI for a significant NIH independent research award.

Definition of Early Stage Investigator:
- Within 10 years of completing terminal research degree or within 10 years of completing medical residency (or the equivalent).
- The NIH corporate policy is to fund R01s of New Investigators and ESIIs at different paylines
- 3 Paylines for R01s Applies only to R01 applications

3. Funding New Investigators

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4. Shortening the Review Time

To enable resubmission, when doable and desirable, 4 months earlier than in the past.

4. Funding the Best Research Earlier

- Abolish A2 applications
4. Percent of R01 Awards by Amendment

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5. Focusing More on Impact and Significance
   - Shorter Applications
   - Template Based Review
   - Score on Impact and Significance
   - Training of Reviewers
6. Attracting the Best Reviewers

Some Successful Strategies

- Move a meeting a year to the West Coast
- Additional review platforms
- Develop a national registry of volunteer reviewers
- Searchable database with 5,000 reviewers
- Provide tangible rewards for reviewers
  - No submission deadlines for chartered members of study sections and frequent reviewers
- Provide flexible time for reviewers
  - Choice of 3 times/year for 4 years or
  - 2 times/year for 6 years

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7. Others

1. Reviewing Transformative Research
2. Reviewing for ARRA (The Stimulus), FDA, Treasury Department and Various Countries
3. Changing Scoring
4. Changing the Order of Reviews
5. Training of Reviewers and SS Chairs

7. Training Study Section Chairs

Clouds on the Horizon

- The Business Model of Many Universities and Medical Schools is not sustainable
- The NIH is becoming a Faculty Employment Agency
- Intra and Extramural mandates and bureaucracy are overwhelming
- Too many Institutes not aligned with today's Science
- Leadership unwilling to make strategic decisions
Coronary Heart Disease
Age-Adjusted Death Rates in U.S.: Actual (blue) vs. Expected (yellow)

- 1,329,000 Projected Deaths in 2000
- 514,000 Actual Deaths in 2000
- 815,000 Deaths Prevented in 2000

Average annual investment per American
~ $3.70

National International Hope