



NIH and YOU: Mission Possible!

NIH Regional Seminar on
Program Funding and Grants Administration

Sally Rockey, PhD
Acting Director, NIH Office of Extramural Research (OER)
Office of the Director

June 25, 2009

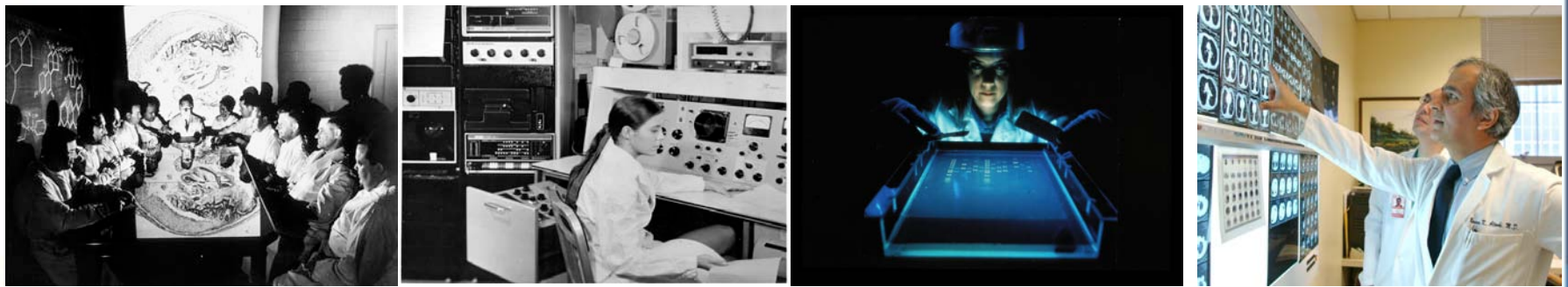




The National Institutes of Health

The 65-Year Mission of NIH

- Section 301 of the PHS Act –“The Secretary shall conduct in the Service and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man . . .”
- ***The NIH is the primary Federal agency for conducting and supporting medical research***





Key Moments in Legislative History

- March 3, 1879 – National Board of Health to lead first Federal medical research effort
- March 3, 1901 – Hygienic Laboratory to investigate matters pertaining to public health
- August 14, 1912 – Public Health Service created to research “diseases of man.”
- August 5, 1937 – NCI created
- July 1, 1944 – Passage of Public Health Service Act, creates first National Institutes of Health
- June 10, 1993 – NIH Revitalization Act passed
- January 15, 2007 – NIH Reform Act Signed



One Hundred Ninth Congress
of the
United States of America

AT THE SECOND SESSION

*Began and held at the City of Washington on Tuesday,
the third day of January, two thousand and six*

An Act

To amend title IV of the Public Health Service Act to revise and extend the authorities of the National Institutes of Health, and for other purposes.

*Be it enacted by the Senate and House of Representatives of
the United States of America in Congress assembled,*

SECTION 1. SHORT TITLE.

This Act may be cited as the “National Institutes of Health Reform Act of 2006”.

TITLE I—NIH REFORM





External Political Factors Driving Growth and Organizational Design of NIH

- World War II
- Academic Medical Centers
- Advances in Methods of Discovery
- Patient Advocates



Science, The Endless Frontier

July 25, 1945:

Question from President Roosevelt to Vannevar Bush, Director,
Office of Scientific Research and Development:

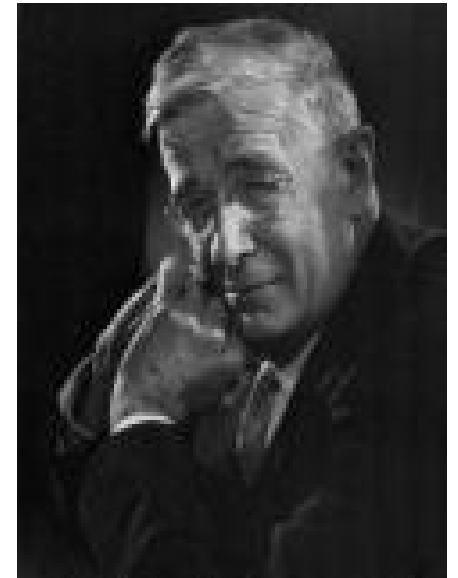
“With particular reference to the war of science against disease, what can be done now to organize a program for continuing in the future the work which has been done in medicine and related sciences?”



Establishing the NIH Model

-Vannevar Bush's Response to FDR in Science, the Endless Frontier:

“The responsibility for basic research in medicine and the underlying sciences, so essential to progress in the war against disease, falls primarily upon the medical schools and universities...the Government should extend financial support to basic medical research in the medical schools and universities.”

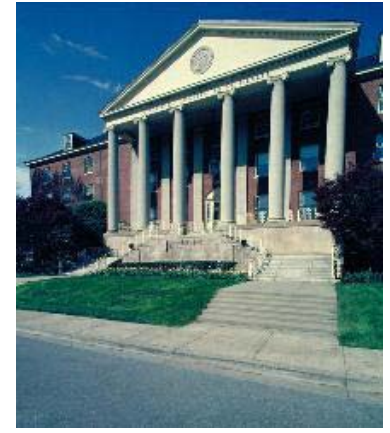




Welcome to the NIH Campus



THEN & NOW

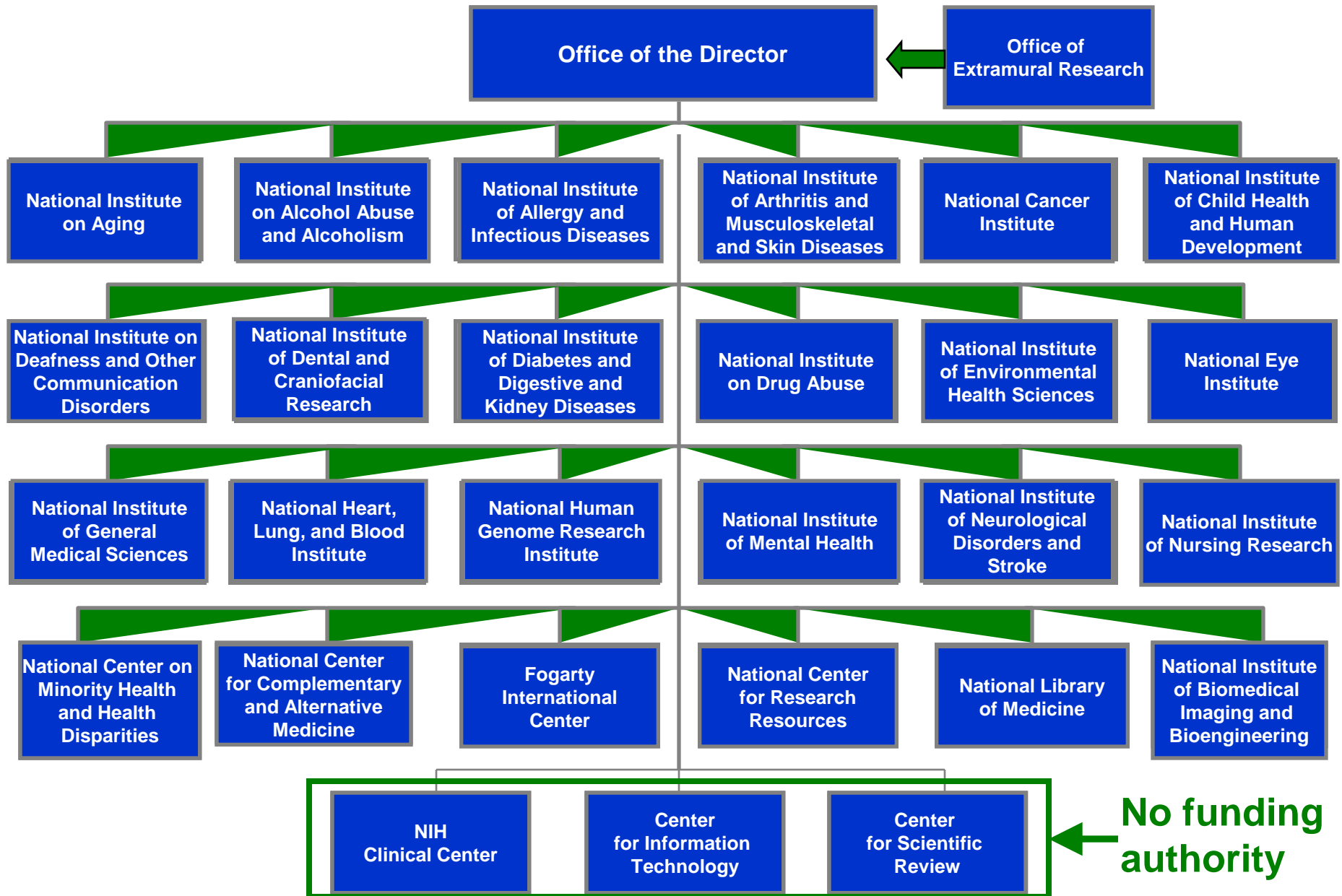


1940

2009



Fitting into the Big Picture





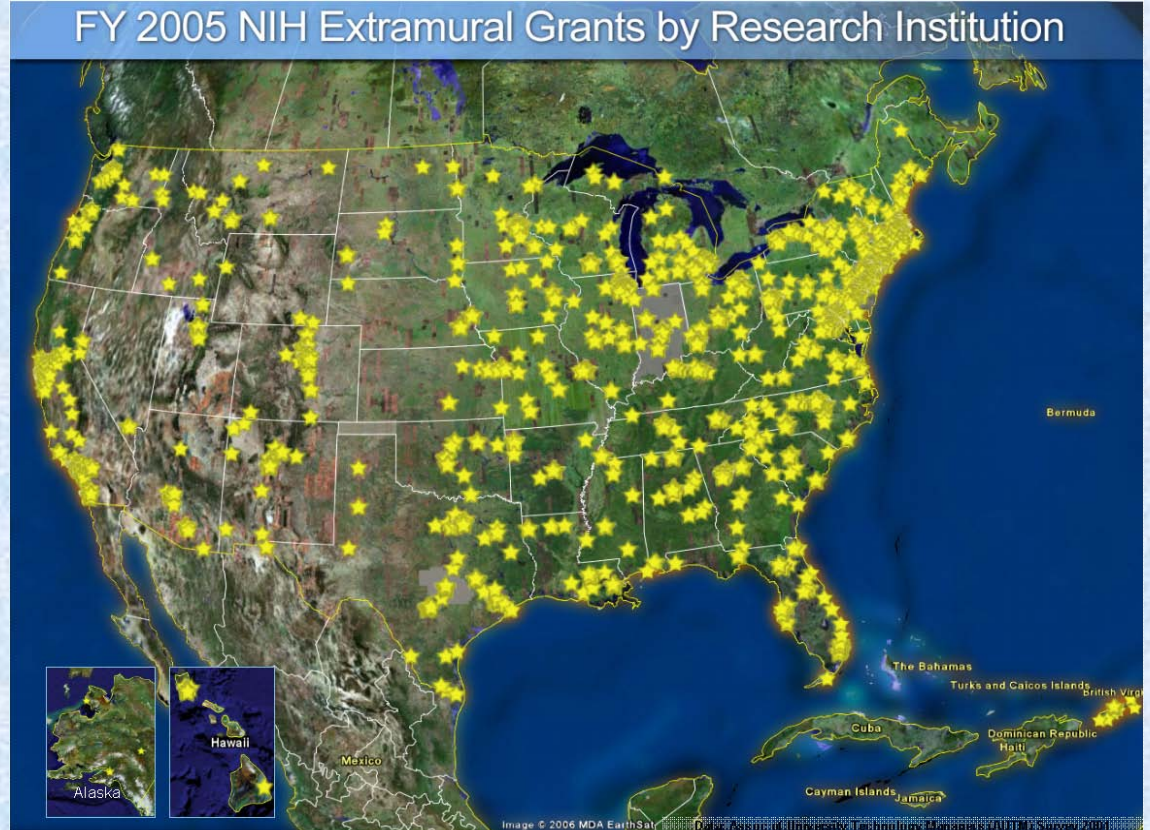
Understanding the Dual Nature of NIH



**NIH is an institution
(Intramural Research)**

~6,000 scientists

~10% of NIH budget



**NIH supports institutions & people
(Extramural Research)**

>3,000 institutions

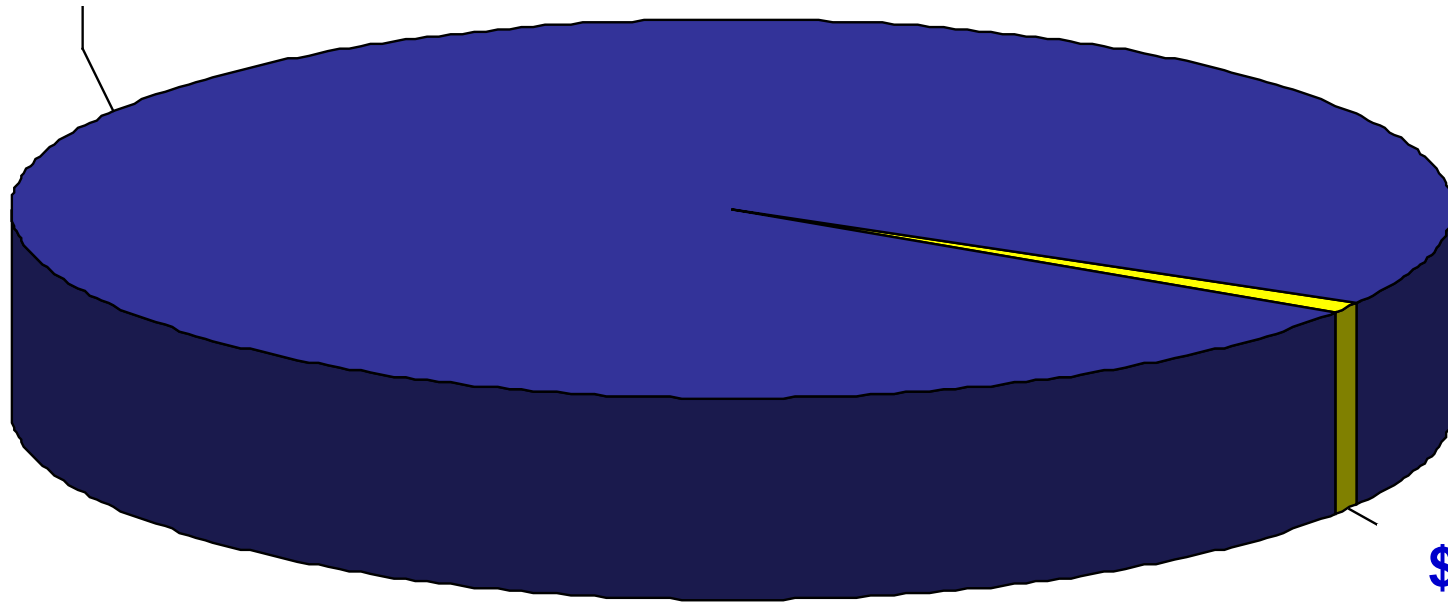
>300,000 scientists & research personnel

~83% of the NIH budget



NIH Gets **Approx. 1%** of U.S. Budget

\$3.1 T



\$30.4 B

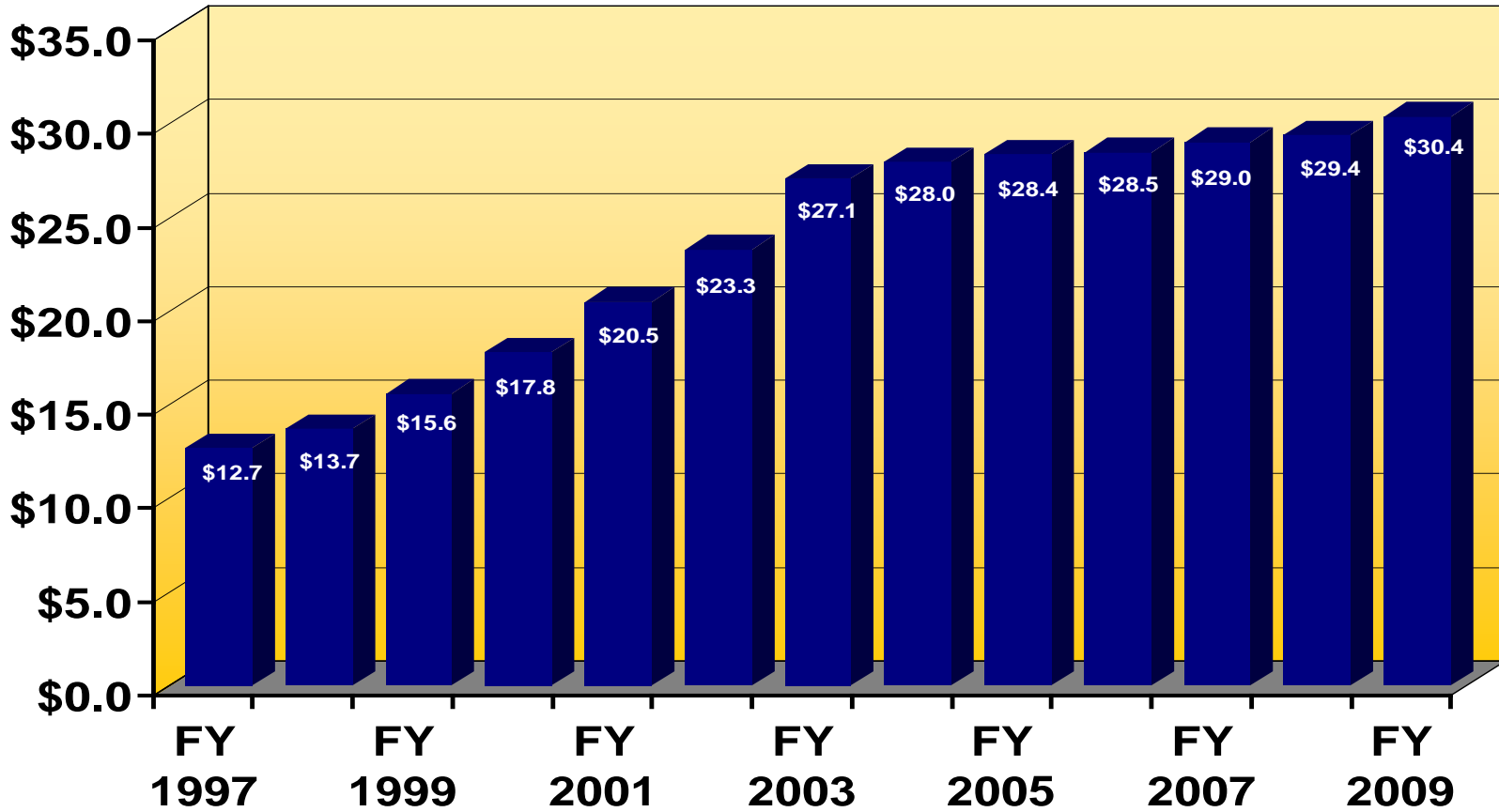
■ NIH

■ Rest of U.S. Budget





NIH Congressional Appropriations FY1997- FY2009 (dollars in billions)





Top 5 States Receiving NIH Awards

#1	CALIFORNIA	\$3.2 B
#2	MASSACHUSETTS	\$2.3 B
#3	NEW YORK	\$1.9 B
#4	PENNSYLVANIA	\$1.4 B
#5	TEXAS	\$1.1 B
	NEVADA	\$20.0 M

Data available on the new Research Portfolio Online Reporting Tool (RePORT): <http://report.nih.gov>



NIH Initiatives and Hot Topics

- Stimulated by ARRA
- Stem Cell Research
- Focus on New Investigators
- New Directions in Peer Review
- Assuring Objectivity in Research





NIH & the ARRA

One Hundred Eleventh Congress of the United States of America

AT THE FIRST SESSION

*Begun and held at the City of Washington on Tuesday,
the sixth day of January, two thousand and nine*

An Act

Making supplemental appropriations for job preservation and creation, infrastructure investment, energy efficiency and science, assistance to the unemployed, and State and local fiscal stabilization, for the fiscal year ending September 30, 2009, and for other purposes.

*Be it enacted by the Senate and House of Representatives of
the United States of America in Congress assembled,*

SECTION 1. SHORT TITLE.

This Act may be cited as the “American Recovery and Reinvestment Act of 2009”.

On Tuesday, February 17, 2009,
President Barack Obama signed the
American Recovery and
Reinvestment Act of 2009 (ARRA)
into law.



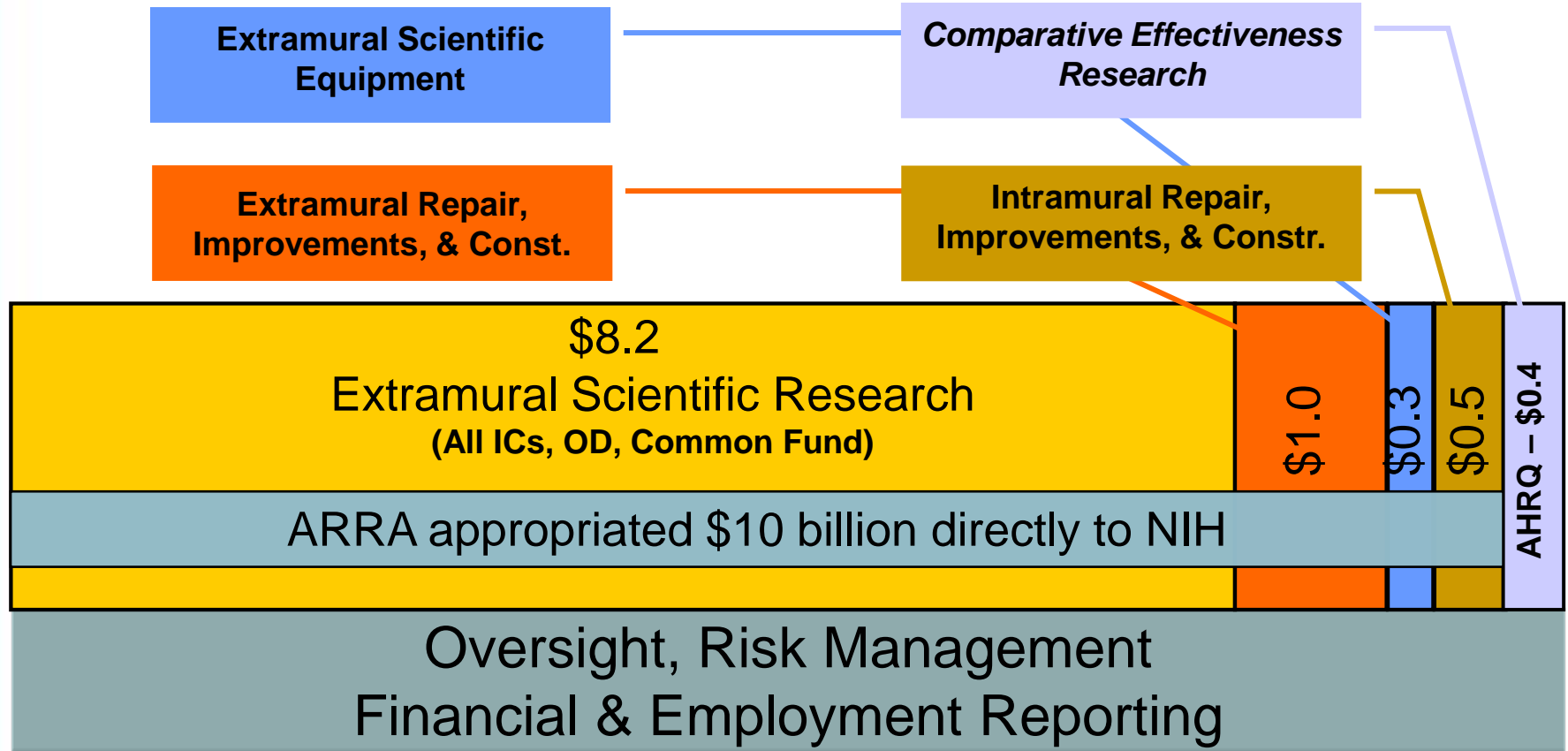
- Stimulate the economy
- Create and preserve jobs
- Advance biomedical research





NIH Allocation of ARRA Funds

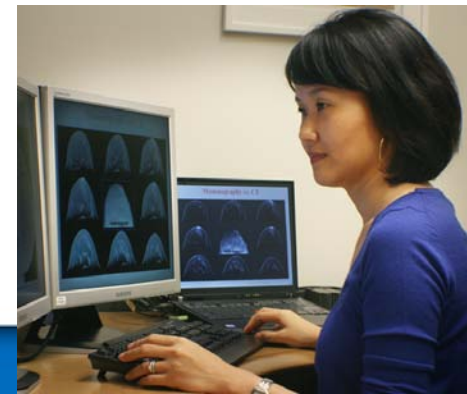
Dollars In Billions





Scientific Research Approach

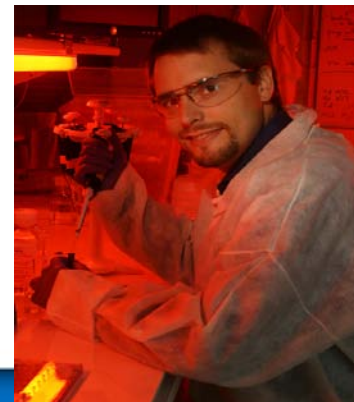
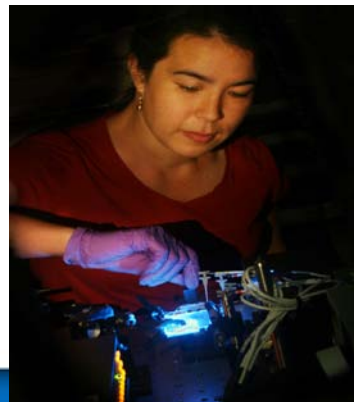
- Stimulate and accelerate biomedical research with existing mechanisms
 - Support already reviewed and found meritorious grants (extend the payline)
 - Supplements to existing grants
 - Competitive – to take on a new direction
 - Administrative – to accelerate existing objectives
- Expand science with new programs





ARRA NIH-Wide Programs

- Challenge Grants
- Grand Opportunities (“GO” Grants)
- Recruit new faculty to conduct research
- Provide summer jobs for high school / college students and teachers to work in science labs - [NIH Guide Notice: NOT-OD-09-060](#)
- Accelerate the tempo of scientific research on active grants through supplements - [NIH Guide Notice: NOT-OD-09-056](#)
- Competitive Revisions consistent with the goals of the Recovery Act - [NIH Guide Notice: NOT-OD-09-058](#)



2009 Tentative Review Timeline for Challenge Grant Applications

For Applicants

Over 20,000 applications received!

Scientific Review Group meetings (rank order scoring)

July 13 - 24

APRIL

MAY

JUNE

JULY

Receipt and referral of grant applications

Apr 27-30

Reviewers receive access to applications & assignments

May 11 - 29

Scores & Summary Statements** available in eRA Commons!!

July 31

**Discussed get overall impact/priority score, resume and summary of discussion, criterion scores, & two or three critiques

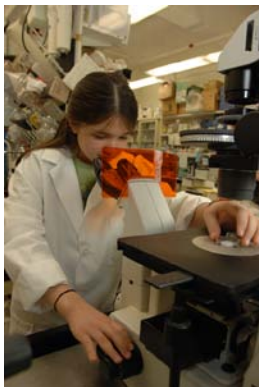
**Not Discussed get criterion scores and two or three critiques

Applications involving stem cells held for review after final guidance issued



Summer Jobs in Research for Students and Teachers

- Engage students and educators in research
- Encourage students to pursue research careers
- Provide summer internships at NIH-funded laboratories for science teachers
 - ~ 1000 awards to virtually every state, \$35.4 m
 - ~ 4,000 jobs for summer '09 and '10





search

>> Advanced Search

- HOME
- HEALTH
- GRANTS
- NEWS
- RESEARCH
- INSTITUTES
- ABOUT NIH

Home

Email this page

NIH and the ARRA

Quick Links

- Mission
- Leadership
- Research Planning
- Budget
- Organization
- History
- Photo Galleries
- NIH Almanac
- Outreach & Education
- Public Involvement
- Small Business Opportunities
- Jobs
- FAQ
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- Contact NIH
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American Recovery & Reinvestment Act

✉ Sign up to receive NIH and the American Recovery & Reinvestment Act e-mail updates.

Overview of the American Recovery and Reinvestment Act of 2009 (Recovery Act). The American Recovery and Reinvestment Act of 2009 (Recovery Act) was signed into law by President Obama on February 17th, 2009. It is an unprecedented effort to jumpstart our economy, create or save millions of jobs, and put a down payment on addressing long-neglected challenges so our country can thrive in the 21st century. The Act is an extraordinary response to a crisis unlike any since the Great Depression, and includes measures to modernize our nation's infrastructure, enhance energy independence, expand educational opportunities, preserve and improve affordable health care, provide tax relief, and protect those in greatest need.

>> Overview of the Recovery Act
<http://www.hhs.gov/recovery/overview/index.html>

RECOVERY.GOV

>> Implementing the Recovery Act
<http://www.hhs.gov/recovery/programs/index.html>

>> Learn more about programs that issue grants under the Recovery Act
<http://grants.nih.gov/recovery/>

ARRA Grant Funding Opps
and Info at
Grants.nih.gov/Recovery

Announcements

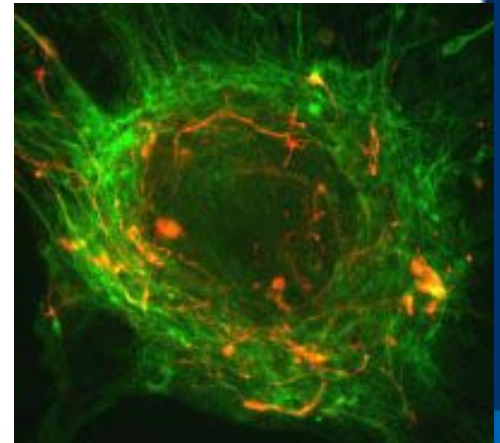
>> Applications for \$1.5 Billion in Recovery Act Funds Now Available
<http://www.nih.gov/news/health/mar2009/od-10.htm>

>> The NIH has designated at least \$200 million in FYs 2009—2010 for a new initiative called the NIH Challenge Grants in Health and Science Research. This new program will support research on topic areas that address specific scientific and health research challenges in biomedical and behavioral research that would benefit from significant 2-year



Stem Cell Research

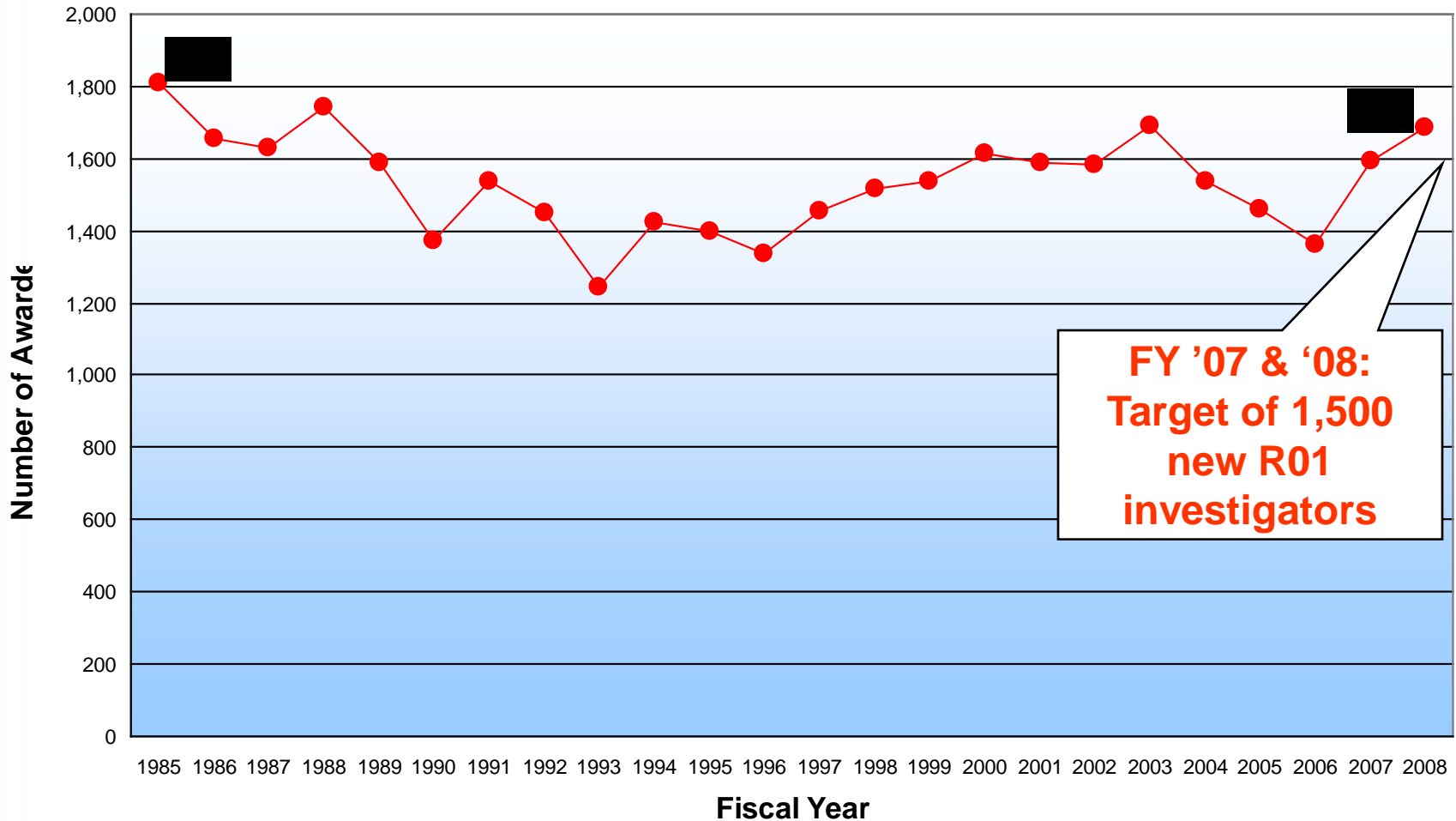
- On March 9, 2009, President Barack Obama issued Executive Order (EO) 13505, entitled [Removing Barriers to Responsible Scientific Research Involving Human Stem Cells](#).
- New NIH guidance is required within 120 days of the date of the EO (July 7, 2009)
- Draft guidance published – 49,000 responses
- Find FAQs, policies, information on the Stem Cell Registry and more at <http://stemcells.nih.gov/policy>.





NIH Exceeds New Investigator Goal in FY 2008

NIH First Time R01-Equivalent Awardees FY 1985-2008



**FY '07 & '08:
Target of 1,500
new R01
investigators**

*R01-Equivalent awards include R01, R23, R29, and R37 grants.





Enhancing Peer Review



Enhancing Peer Review at NIH



A Self-Study by the NIH in Partnership with the Scientific Community to Strengthen Peer Review in Changing Times

Keeping the Goal in Mind:

**“Fund the Best Science, by the Best Scientists,
with the Least Administrative Burden.”**

NIH Director, Dr. Elias A. Zerhouni



Enhancing Peer Review: Summary of Recommendations

Priority 1: Engage the Best Reviewers

Increase Flexibility to Better Accommodate Reviewers

Recruit Reviewers

Acknowledge Reviewers more formally

Compensate Reviewers Time and Effort

Improve Review Quality with Training

Priority 2: Improve the Quality & Transparency of Review

Modify Rating System to Focus on Specific Review Criteria

Align Summary Statement with Review Criteria

Shorten and Align Application with Review Criteria

Priority 3: Ensure Balanced & Fair Reviews Across Scientific Fields and Career Stages

Support for Early Stage Investigators

Review of Established Investigators

Enhanced Review of Clinical Research

Expand Awards Encouraging "Transformative Research"

Reduce Need for Resubmissions

Priority 4: Continuous Review of Peer Review



More at: <http://enhancing-peer-review.nih.gov>



Health Service (PHS) Regulation

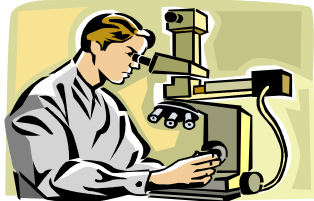
42 CFR Part 50, Subpart F

- Responsibility for the identification and management of investigators' FCOI is placed with the institution, which oversees the investigator's activities.
- As the grantor agency, NIH has primary responsibility for overseeing institutional compliance with these requirements.

Note: Use of the eRA Commons FCOI module/reporting tool will be mandatory as of July 1, 2009 - [NIH Guide Notice NOT-OD-09-072.html](http://www.fda.gov/oc/ohrt/NIH_Guide_Notice_NOT-OD-09-072.html)

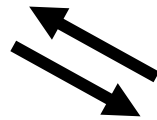


NIH has Oversight...Institutions Manage



Investigator

Disclosure
Compliance

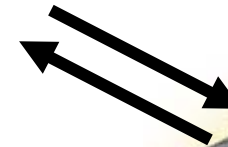


Institutional
Policy
Implementation
Management
Oversight



Institution

Compliance
(including accurate
& timely reporting)



NIH



Oversight

PHS regulation 42 CFR Part 50, Subpart F
1995





Advance Notice of Proposed Rulemaking (ANPRM)

- Developed by NIH as one option under HHS consideration to gain public input on potential changes to the FCOI regulation via Federal Register
- Could subsequently lead to NPRM and a new Final Rule
- Current draft addresses various topics including:
 - expanding the scope of regulation and disclosure of interests;
 - definition of Significant Financial Interest;
 - identification and management of conflicting interests by institutions;
 - assuring institutional compliance;
 - requiring institutions to provide additional information; and
 - defining institutional conflict of interest
- Comments due July 07, 2009
- NIH Guide Notice: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-099.html>





FCOI Resources and Contacts

- Web Based Tutorial For Investigators:
<http://grants.nih.gov/grants/policy/coi/tutorial/fcoi.htm>
- New Pilot New Pilot Program Announced for Reporting FCOI: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-001.html>
- Division of Grants Compliance and Oversight Home page with Updated FAQs:
<http://grants.nih.gov/grants/compliance/compliance.htm>
- Dedicated e-mail: FCOIcompliance@mail.nih.gov



About Grants

- Grants Process & Award Data
- [Grant Application Basics](#)
 - [Grants Process Overview](#)
 - [Types of Grant Programs](#)
 - [How to Apply](#)
 - [Peer Review Process](#)
 - [Award Management](#)
 - [NIH Financial Operations \(w/Funding Strategies\)](#)
 - [Award Information & Data](#)



- Electronic Grants
- [Electronic Research Admin \(eRA\)](#)
 - [eRA Commons](#)
 - [Applying Electronically](#)

Grants Policy

- [Policy & Guidance](#)
- [Compliance & Oversight](#)
- [Research Involving Human Subjects](#)
- [Office of Animal Laboratory Welfare \(OLAW\)](#)
- [Animals in Research](#)

Funding

- Funding Opportunities
- Search Funding Opportunities:
[NIH Guide for Grants and Contracts](#)
-
-

- [Funding Opportunities \(RFAs, PAs\) & Notices](#)
 - [Unsolicited Applications \(Parent Announcements\)](#)
-
- NEW** [Recovery Act Opportunities](#)
 - [Research Training & Career Development](#)
 - [Small Business \(SBIR/STTR\)](#)
 - [Contract Opportunities](#)
 - [NIH Loan Repayment Programs](#)

Forms & Deadlines

- [Forms & Applications](#)
- [Submission Dates / Deadlines](#)
- [Submitting Your Application](#)

NIH-Wide Initiatives

- [New and Early Stage Investigators](#)
- [Multiple Principal Investigators](#)
- [Genome-Wide Association Studies \(GWAS\)](#)
- [NIH Roadmap for Medical Research](#)
- [NIH Blueprint for Neuroscience Research](#)

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News & Events

News Flashes

- NEW** [Updated Guidelines and Critiques for Reviewers](#)
 - [NIH Web Page Hosts ARRA-Related Funding Opportunity Announcements, Resources, & FAQs](#)
 - [FY2009 Update on Salary Limitation on Grants, Cooperative Agreements, & Contracts](#)
 - [Having Trouble with Your Electronic Application Submission?](#)
- [More News...](#)

Hot Topics

- [Enhancing Peer Review](#)
- [NIH Public Access](#)
- [NIH Policy Notices](#)

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- [NIH Guide LISTSERV](#)
- [SBIR/STTR LISTSERV](#)



Making the Mission Possible!

From mapping chromosomes within the Human Genome Project...
to discovering drugs such as Tamoxifen, the first drug found to prevent breast cancer in women at high risk.

From trials on the effect of a low fat diet on swiftly reducing blood pressure... to developing the first vaccine capable of protecting young children against typhoid fever. (16 million people worldwide develop typhoid each year and 600,000 die from it, mainly from developing countries without adequate sewage and sanitation.

From a consumer-friendly database, ClinicalTrials.gov, with information on more than 4,000 Federal and private medical studies involving patients and others at more than 47,000 locations nationwide... to development, implementation, and continuous improvement of an NIH electronic grant application submission, receipt, and management system.

The NIH values its partnerships with academia and private industry, which all play crucial roles in uncovering knowledge that will lead to better health for everyone.

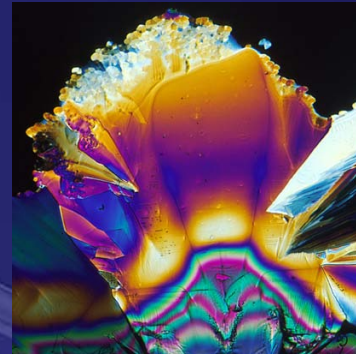


NIH and YOU! Building Partnerships in Biomedical & Behavioral Research!

The NIH supports research endeavors worldwide, while providing opportunities for today and tomorrow's researchers to share their vision and innovation.



The future rests on your ideas and support of the process!



NIH

*Transforming medicine
through discovery*

