



# NHLBI Research Funding and Update on Priorities



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National Heart, Lung, and Blood Institute



March 5, 2010



National Heart  
Lung and Blood Institute

# Overview

## History & Organization

- NIH and NHLBI

## Budget

- NIH and NHLBI

## Strategic plan

- Goals/examples

## Training

## Funding Options

## Payplan/Success Rates



# Welcome to the Birthplace of the NIH: Circa 1887



Located in a small attic room in the Marine Hospital; Staten Island, New York

On October 31, 1940, President Franklin Roosevelt dedicated the first six buildings of NIH.

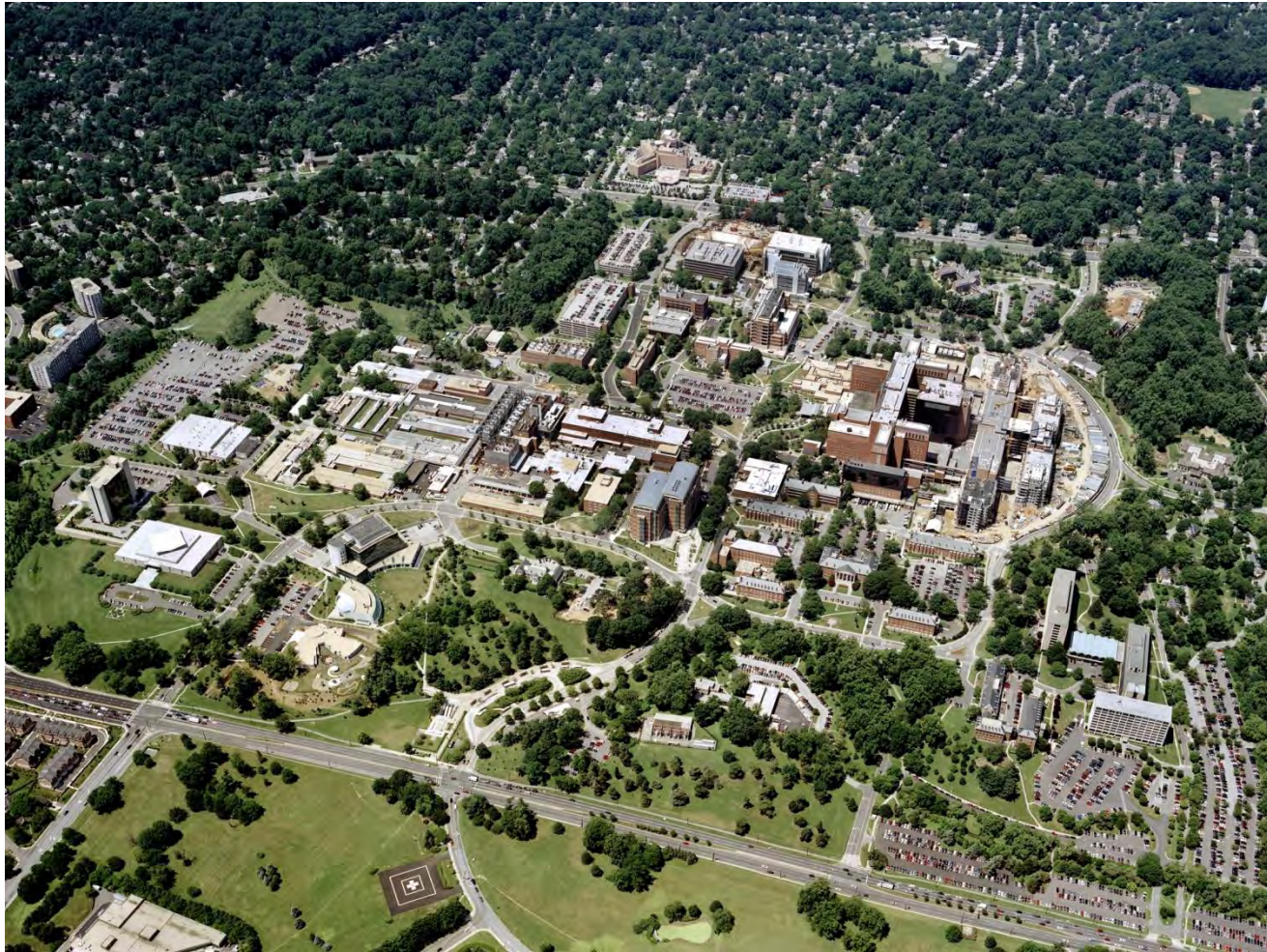


# ...And to NIH: Circa 2010

- One of 12 agencies under the Department of Health and Human Services
- Comprised of 27 Institutes and Centers (IC)

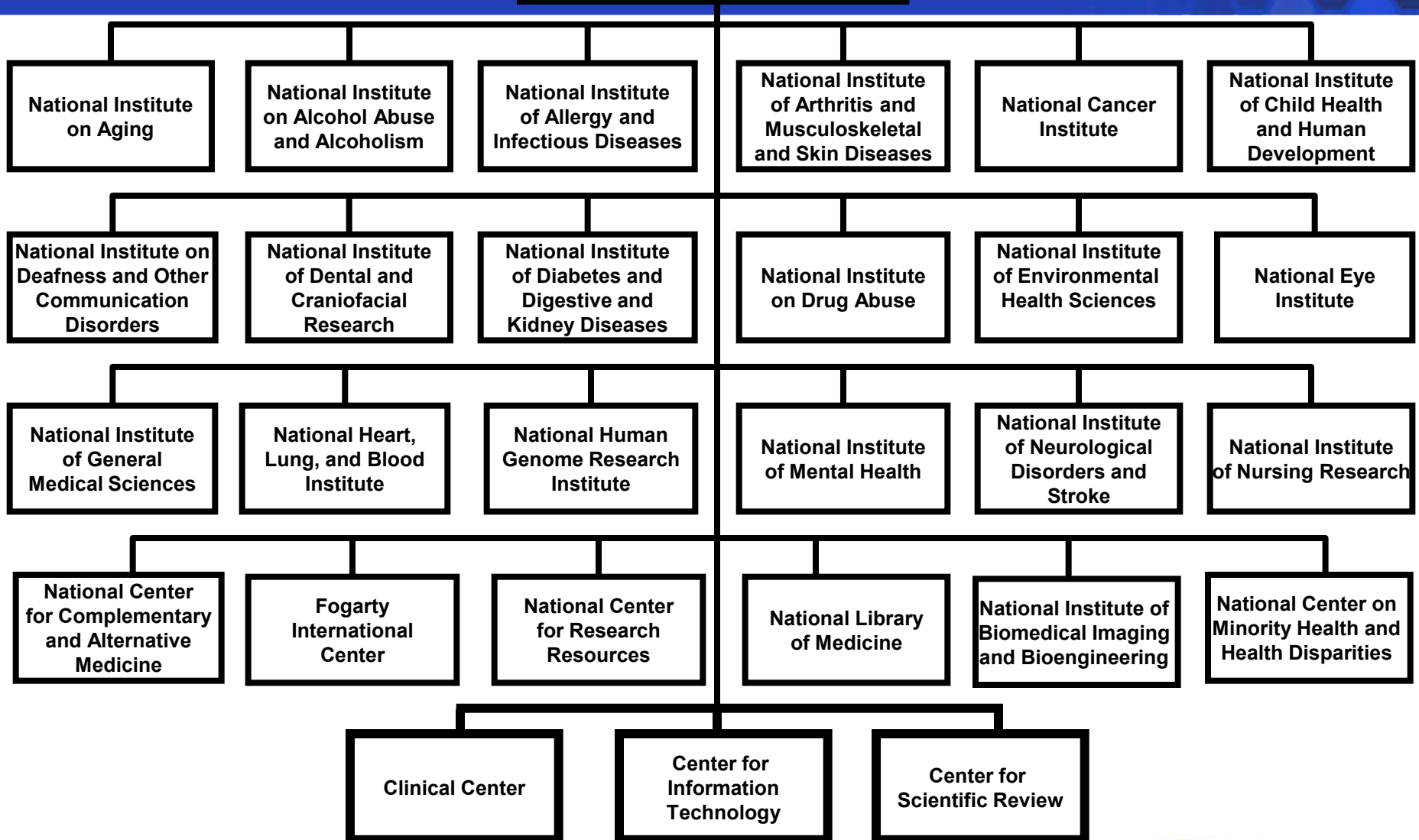


# NIH Campus

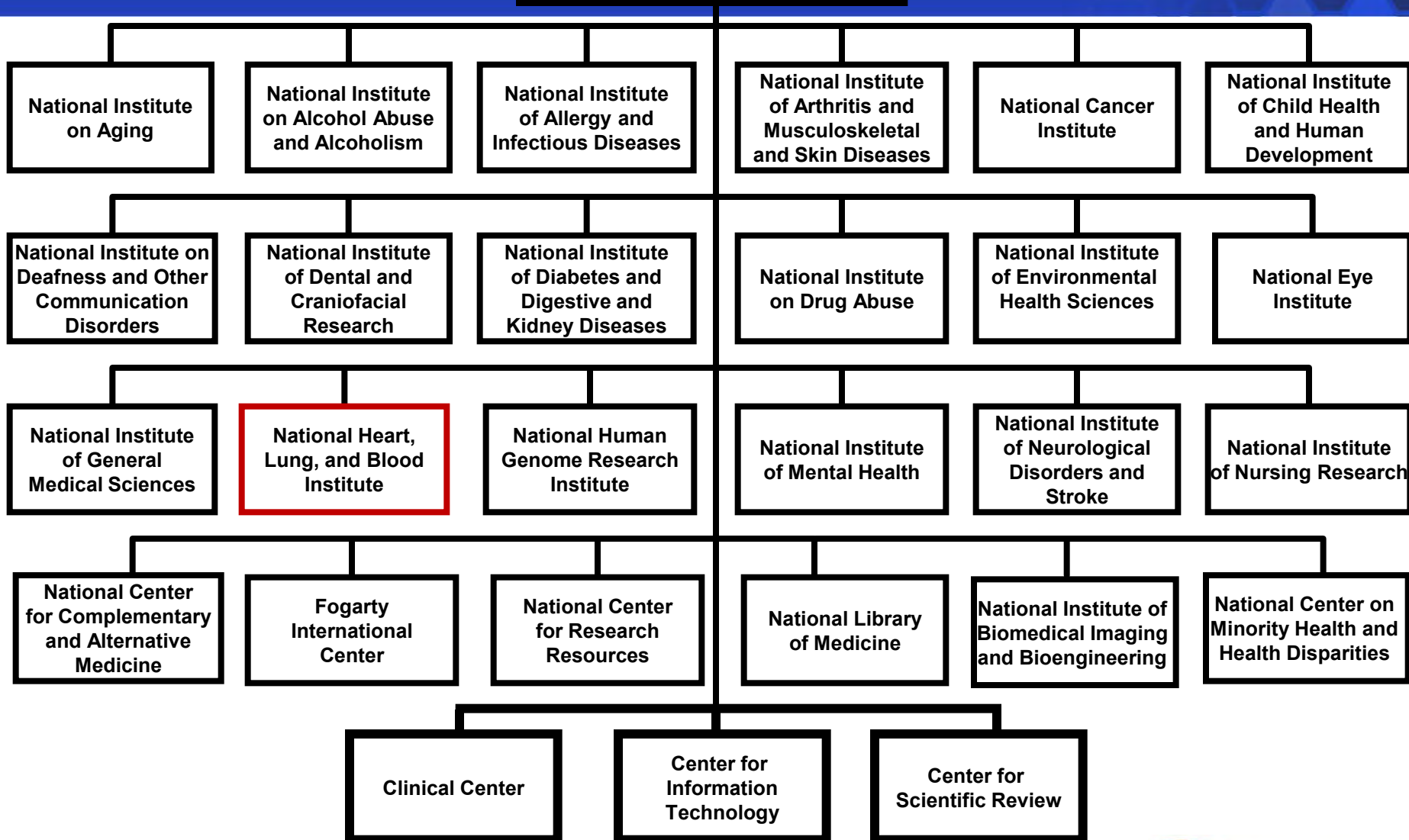


Office of the Director

Dr. Francis Collins

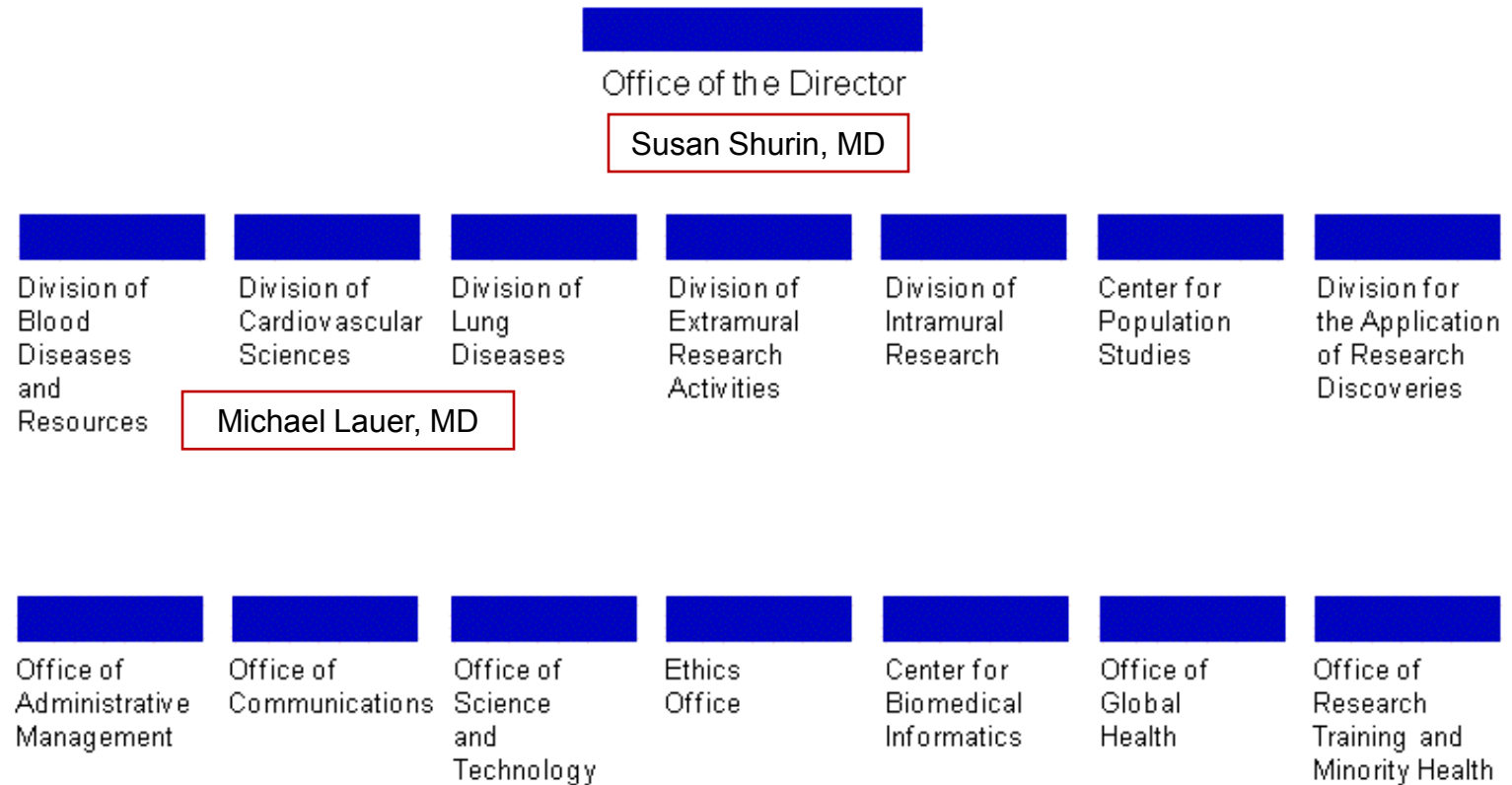


# Office of the Director

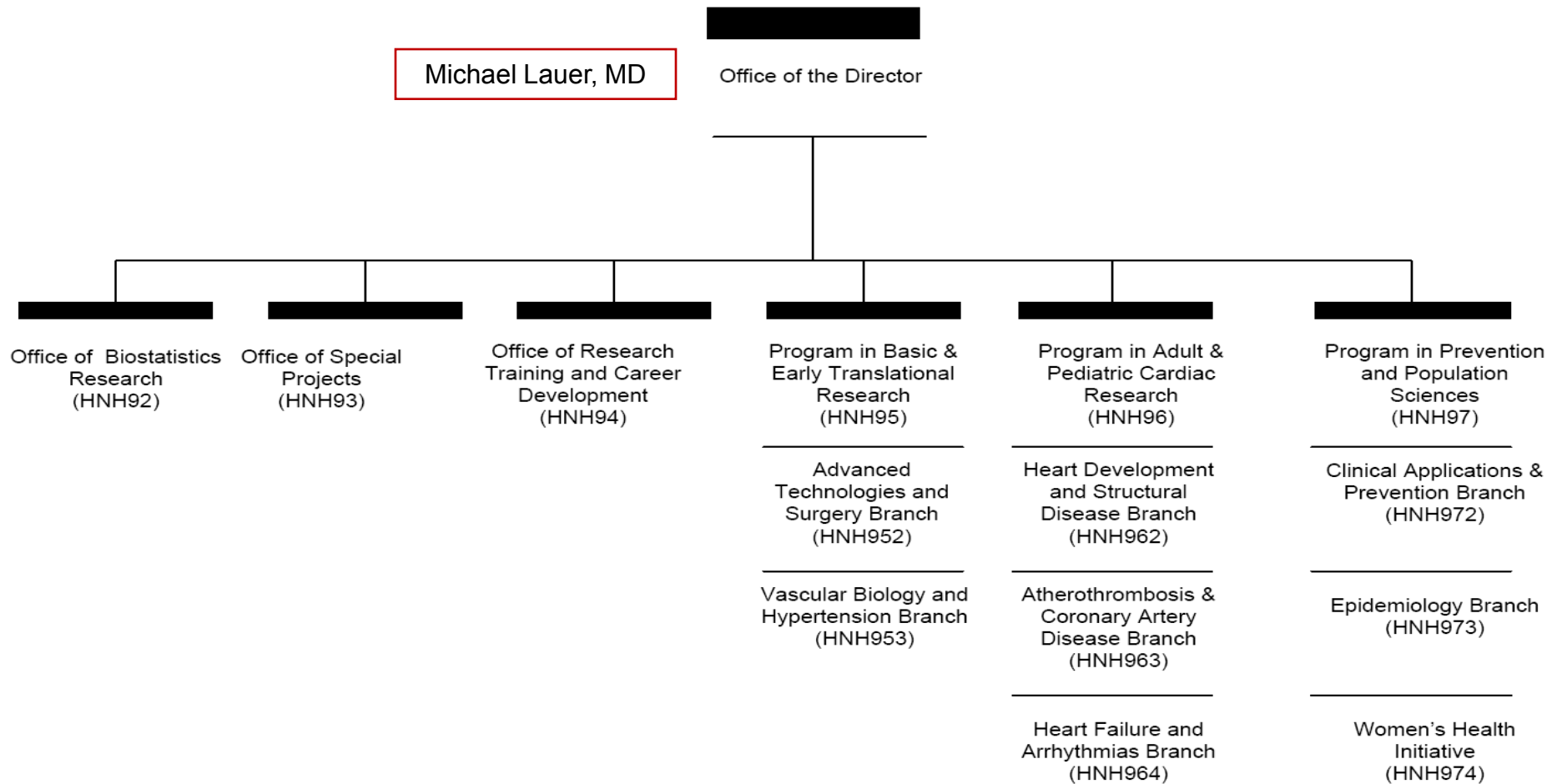




# NHLBI Organizational Chart

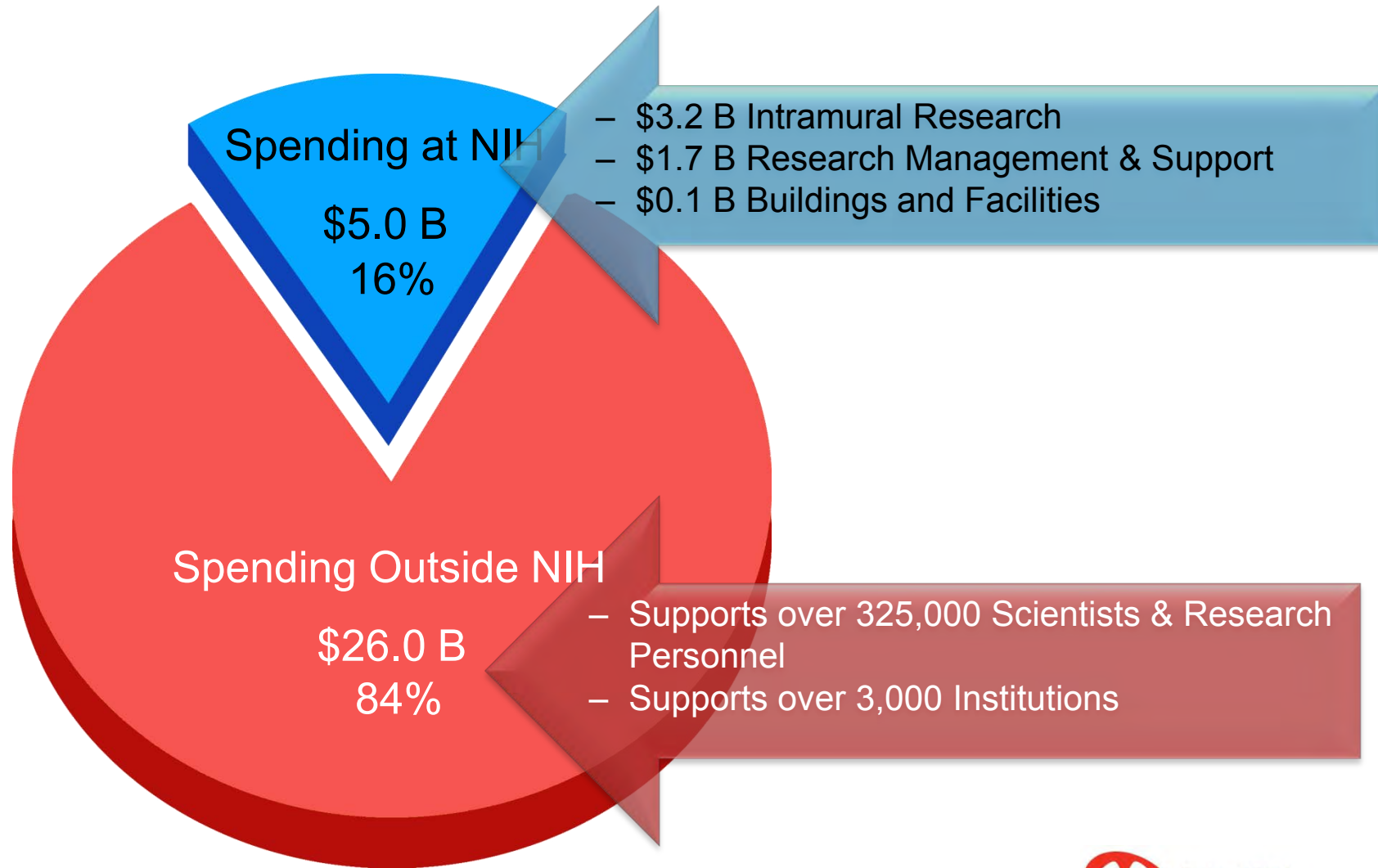


# Division of Cardiovascular Sciences



# NIH Extramural & Intramural Funding

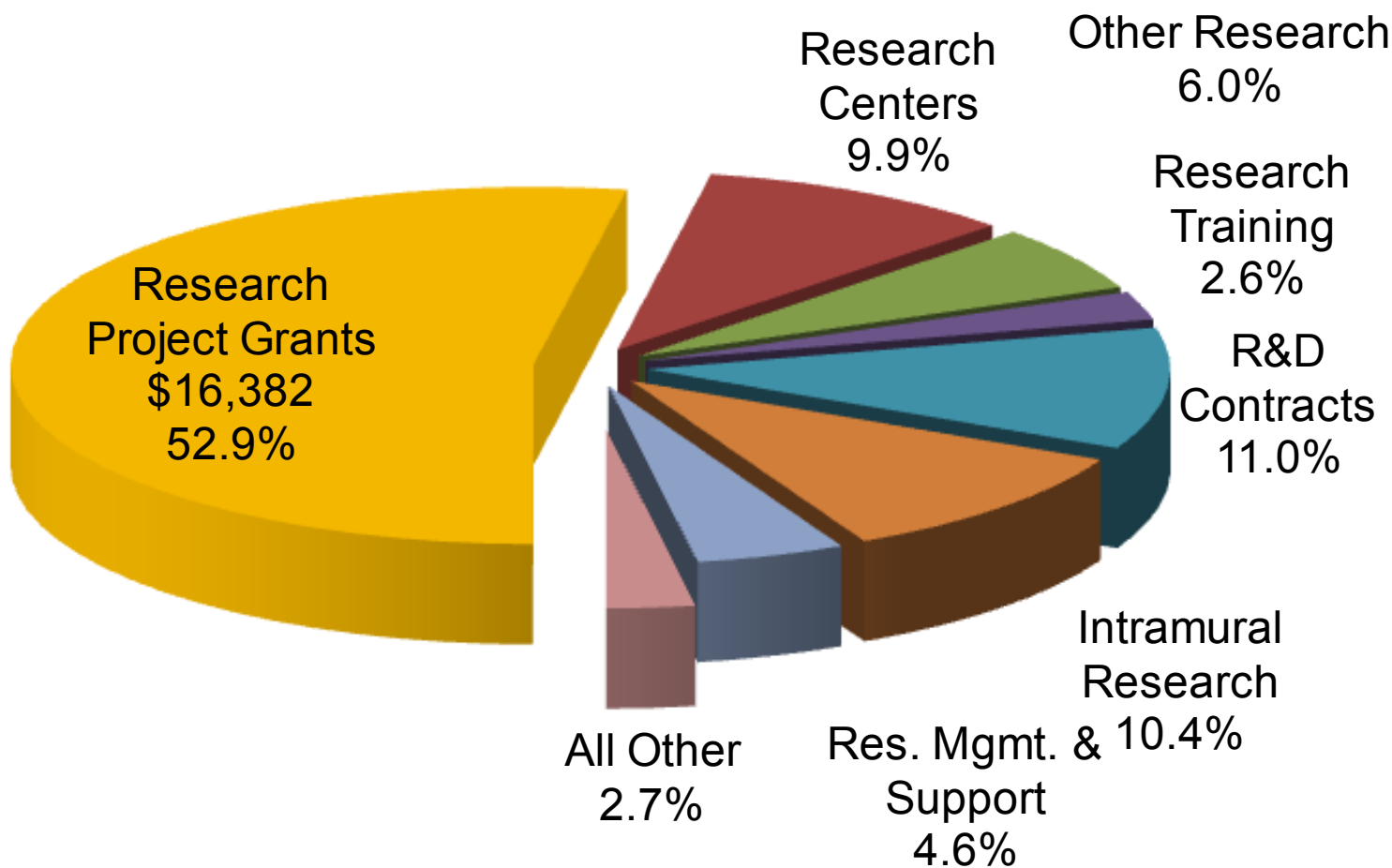
## FY 2010 Final Budget: \$30.988 Billion\*



\* Includes \$150 million from the Special type 1 Diabetes appropriation.

# NIH Funding Distribution by Mechanism

## FY 2010 Budget \$30.988 Billion



# NHLBI Non-ARRA Budget – FY 2009 (Dollars in Thousands)

	FY 2009 Actual
Res. Project Grants:	
Noncompeting & Competing	1,959,738
<b>Subtotal</b>	<b>\$1,959,738</b>
SBIR/STTR	76,400
<b>Subtotal, RPGs</b>	<b>\$2,036,138</b>
Research Centers, Careers, Other	221,154
Research Training	96,579
Research Contracts	366,010
<b>Total, Extramural</b>	<b>\$2,719,881</b>
Intramural Research	181,737
Res. Mgmt & Support	114,071
<b>Total, NHLBI</b>	<b>\$3,015,689</b>

# Number of Research Grants and Training Positions FY 2009

FY 2009  
Actual

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## Research Grants

Noncompeting	2,921
Competing	968

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<b>Subtotal</b>	<b>3,889</b>
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SBIR/STTR	172
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<b>Subtotal, RPGs</b>	<b>4,061</b>
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Research Centers	43
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Research Careers	572
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Other Research	144
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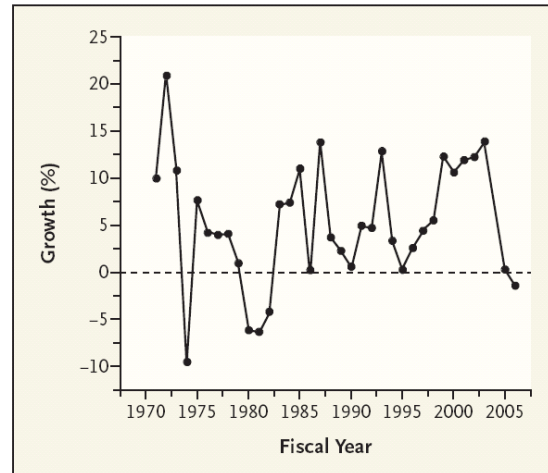
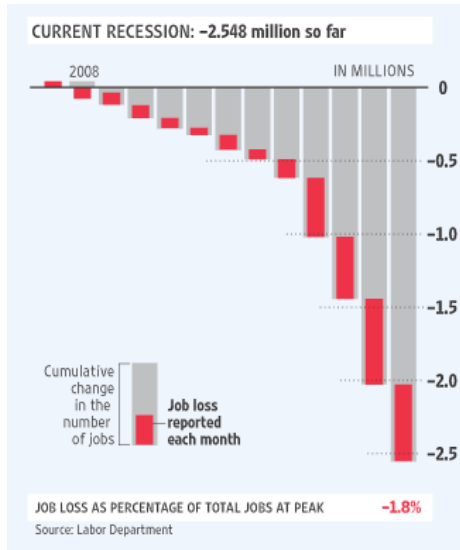
<b>Total, Res. Grants</b>	<b>4,820</b>
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## Full Time Training Positions

Research Training	1,989
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Research Contracts	216
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# Recession: Global, National, and Local



Annualized Growth of the NIH Budget, 1971 to 2005.

FEBRUARY 9, 2009, 6:37 A.M. ET

## IMF Chief Says Nations in 'Depression'

Article Comments

Email Printer Friendly Share Yahoo Buzz Text Size

By BOB DAVIS and ELFFIE CHEW

International Monetary Fund chief Dominique Strauss-Kahn said the world's advanced economies -- the U.S., Western Europe and Japan -- are "already in depression," and that the IMF could slash its global growth forecasts further. The "worst cannot be ruled out," he said.

The IMF managing director's comments to reporters after a speech in Kuala Lumpur, Malaysia, represent the most dire estimate thus far of the state of the global economy by a major political figure, and were far more pessimistic than forecasts released by the IMF as recently Jan. 28.



Political figures generally avoid using the word depression because of the association with the Great Depression of the 1930s, when unemployment hit 25% in the U.S. and economic output fell even more steeply. Last week, when British Prime Minister Gordon Brown used the word "depression" to describe the global economy, his aides quickly said it was a slip of the tongue.

In the U.S., chief White House economic adviser Lawrence Summers said that while the economic situation was serious, it wasn't as bad as Mr. Strauss-Kahn seemed to suggest.

The New York Times

### Economy

WORLD U.S. N.Y. / REGION BUSINESS TECHNOLOGY SCIENCE HEALTH SPORTS OPINION

Search Business Financial Tools More in Business

News, Stocks, Funds, Companies Go Select a Financial Tool World Business Markets

#### U.S. Loses 533,000 Jobs in November



# American Recovery & Reinvestment Act (2009): ARRA

111TH CONGRESS  
1ST SESSION

## H. R. 1

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 10, 2009

Ordered to be printed with the amendment of the Senate  
[Strike out all after the enacting clause and insert the part printed in *italics*]

## AN ACT

Making supplemental appropriations for job preservation and creation, infrastructure investment, energy efficiency and science, assistance to the unemployed, and State and

RECOVERY.GOV

HOME | ABOUT | IMPACT | ANNOUNCEMENTS | FAQ | CONTACT US

### YOUR MONEY AT WORK

The American Recovery and Reinvestment Act will be carried out with full transparency and accountability -- and Recovery.gov is the centerpiece of that effort. In a short video, President Obama describes the site and talks about how you'll be able to track the Recovery Act's progress every step of the way.



[privacy policy](#) | [download .mp4](#) | [also available here](#)

Where is Your Money Going?

Welcome to Recovery.gov

Accountability and

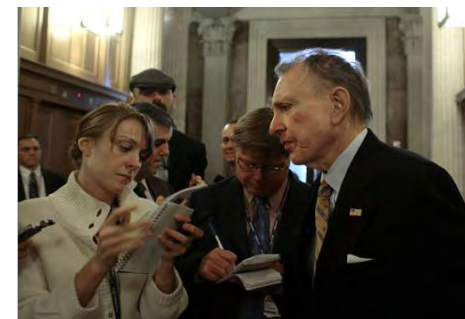
"All the News  
That's Fit to Print"

# The New York Times

### Late Edition

New York: Today, sun, then cloudy, high 38. Tonight, a period of rain and snow, low 33. Tomorrow, decreasing clouds, brisk, high 42. Yesterday, high 29, low 19. Weather map, Page B8.

## Specter, a Fulcrum of the Stimulus Bill, Pulls Off a Coup for Health Money





# NIH ARRA Appropriations

\$10 Billion in new appropriations

\$1B for facility construction and renovation

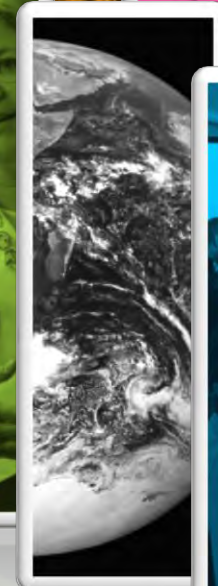
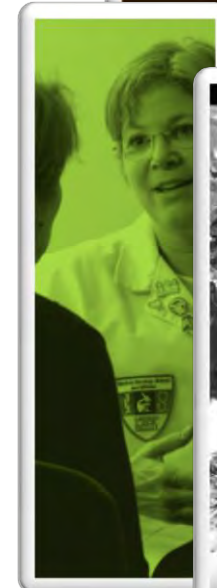
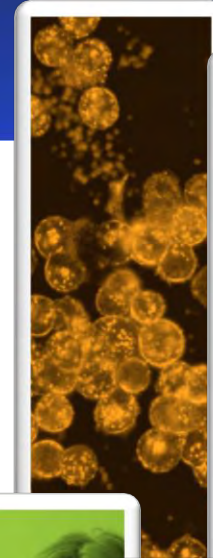
\$300M for shared instrumentation

\$8.2B for research

\$500M for Buildings and Facilities, including  
new construction

# Dr. Collins' Major Opportunities

- Applying high throughput technologies to understand fundamental biology, and to uncover the causes of specific diseases
- Translating basic science discoveries into new and better treatments
- Putting science to work for the benefit of health care reform
- Encouraging a greater focus on global health
- Reinvigorating and empowering the biomedical research community



# NHLBI Mission Statement

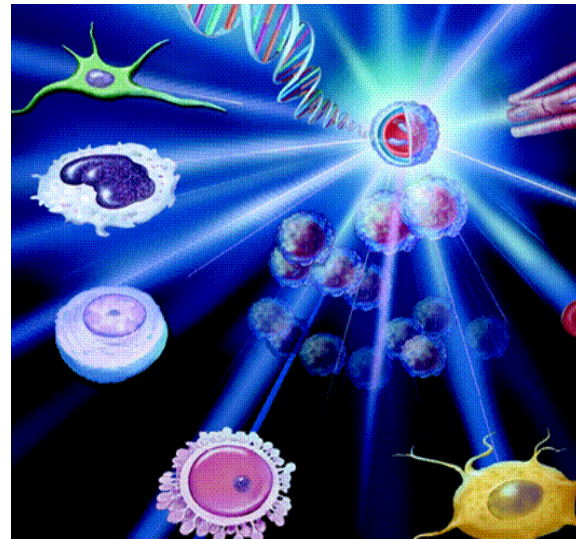
- NHLBI provides global **leadership** for a **research, training, and education** program to promote the prevention and treatment of heart, lung, and blood diseases and enhance the health of all individuals so that they can live longer and more fulfilling lives.
- The NHLBI stimulates **basic** discoveries about the causes of disease, enables the **translation** of basic discoveries into clinical practice, fosters training and mentoring of emerging scientists and physicians, and communicates research advances to the public.
- It creates and supports a robust, collaborative research infrastructure in **partnership with private and public organizations**, including academic institutions, industry, and other government agencies.
- The Institute **collaborates** with patients, families, health care professionals, scientists, professional societies, patient advocacy groups, community organizations, and the media to promote the application of research results and leverage resources to address public health needs.
- The NHLBI also collaborates with international organizations to help reduce the burden of heart, lung, and blood diseases worldwide.

# NHLBI Strategic Plan Goal 1

Improve understanding of the molecular and physiologic basis of health and disease. Use that understanding to develop improved approaches to disease prevention, diagnosis and treatment.

*Form → Function*

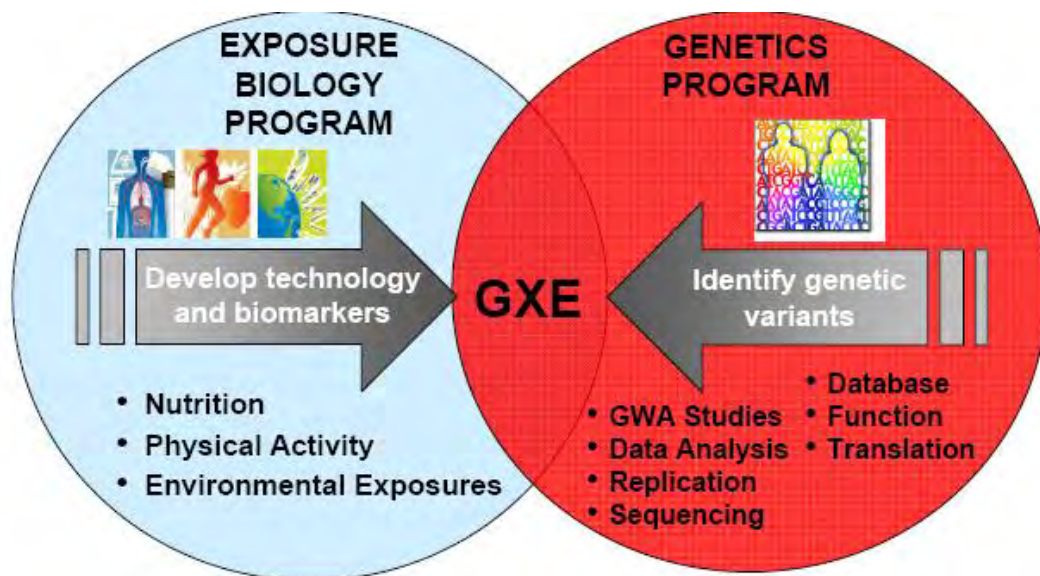
Example: Using echo and advanced imaging to uncover the pathophysiology of atrial fibrillation or valvular heart disease



# NHLBI Strategic Plan Goal 2

To develop personalized preventive and therapeutic regimens for cardiovascular, lung, and blood diseases.

*Function → Cause*

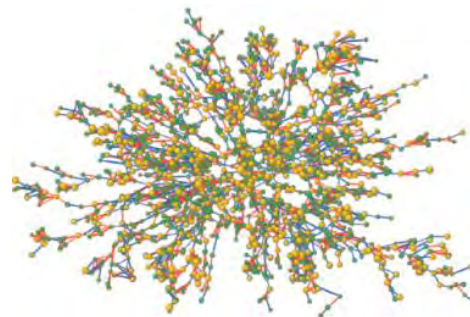
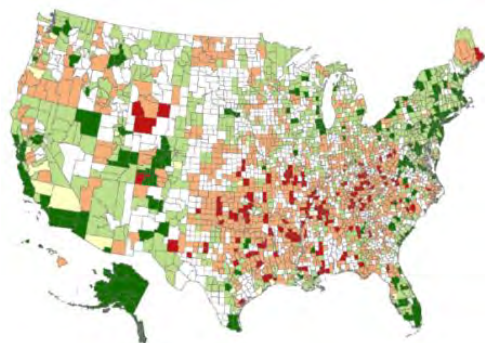


## NHLBI Trials

BARI 2D  
CLEVER  
CORAL  
ACCORD  
FREEDOM  
STICH  
TOPCAT  
CUBANA  
HF-ACTION  
POWER

# NHLBI Strategic Plan Goal 3

Generate an improved understanding of the processes involved in translating research into practice and use that understanding to enable improvements in public health and to stimulate further scientific discovery. *Cause* → *Cures*



# Opportunities for Extramural Research

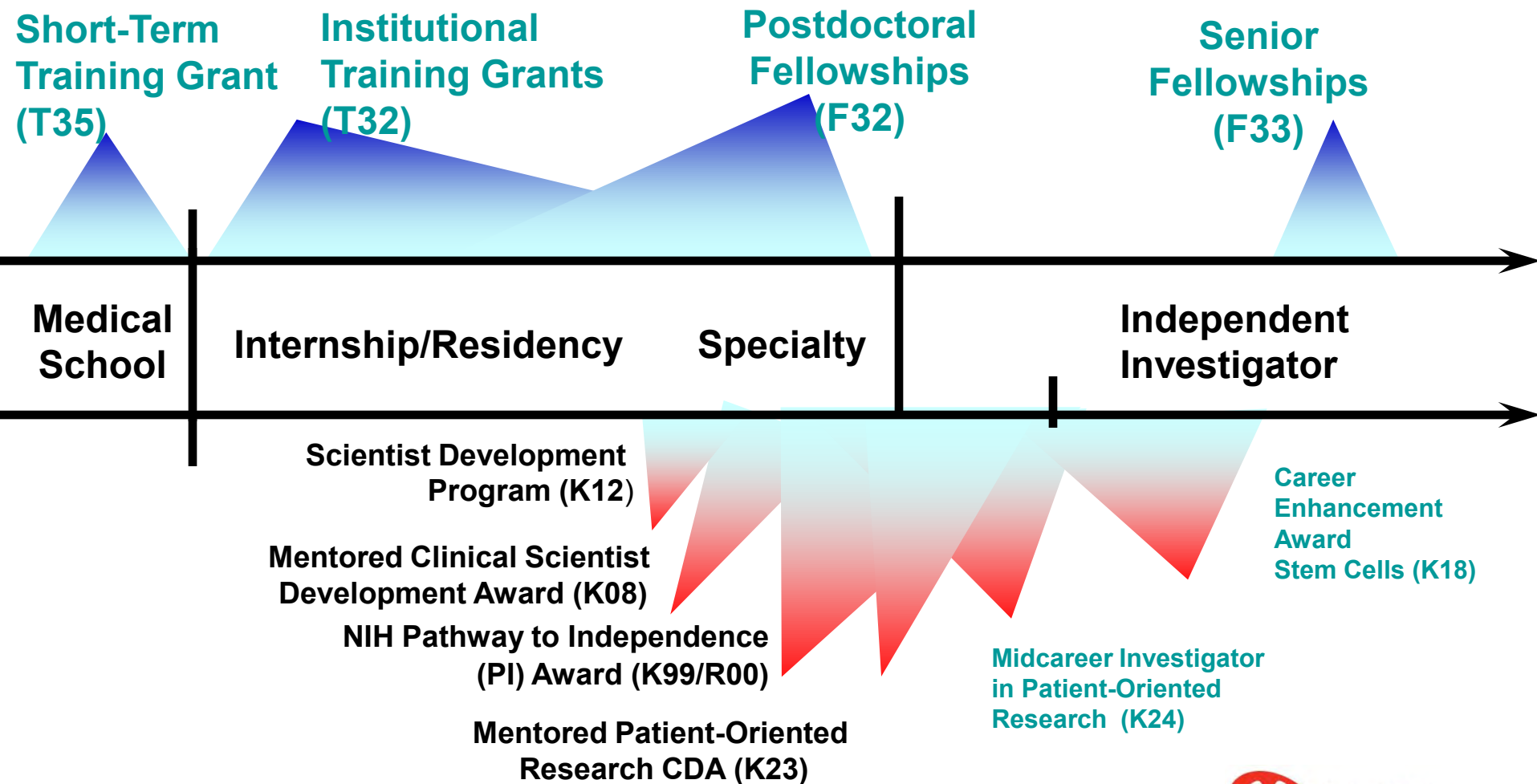
- Investigator-initiated
  - Majority of NHLBI budget
  - Research Project Grants (e.g. R01s, R21s)
  - Less than \$500K vs. >\$500K
- NHLBI-initiated (special circumstances)
  - RFA Programs
  - Specialized Review
  - Set Aside Funds
  - RFPs (Contracts)

# Research Training & Career Development Programs

- Train the next generation of research scientists
- Create competitive & successful researchers
- Ensure new training programs for new scientific domains (computational biology, imaging researchers)
- Support development of new disciplines
- Support and expand research training activities in minority populations
- There is an ongoing need, irrespective of budget



# Awards for Individuals with a Health-Professional Doctorate



# Spectrum of Research Training & Career Development Awards

Graduate & Medical School	Postgraduate Research Training Fellowships	Transition to Established Investigator	Established Investigator
<p>T32 Institutional award</p> <p>T32 Minority Institutions</p> <p>F30 MD/PhD</p> <p>F31 Minority students &amp; individuals with disabilities</p> <p>T35/R25 Short-term training institutional award for minority students</p>	<p>F32 Individual award</p> <p>T32 Institutional award</p> <p>T32 Minority Institutional award</p> <p>Program Length 2-3 years</p>	<p>K08</p> <p>K23</p> <p>K25</p> <p>K02</p> <p>K01</p> <p>K99/R00</p> <p>K12 Programs</p> <p>Program Length 3-5 years</p>	<p>F33</p> <p>K24</p> <p>K25</p>

# How NHLBI Establishes Scientific Priorities

- Mission statement
- Strategic Plan
- Portfolio Analysis
- Gaps in Science

Other Factors
Feasibility
Innovation
Likelihood that entity outside Institute would support
Multidisciplinary Nature
Potential impact on individual health
Potential impact on national health care expenditures
Potential impact on population health
Qualifications and track record of the proposer
Quality of proposed methods
Quality of writing and organization of proposal
Relevance to global agenda
Relevance to mission and strategic plan
Research need/Lack of studies
Study cost
Uniqueness or timeliness of opportunity

# RFA Development: Formal Process

NHLBI Strategic Plan



Scientific advice (literature, discussions with investigators, **workshops**)



Staff development (informal internal networking and discussions)



Idea Forum

# Formal Process

Idea Forum



Board of External Experts (BEE)



NHLB Advisory Council



Director's decision



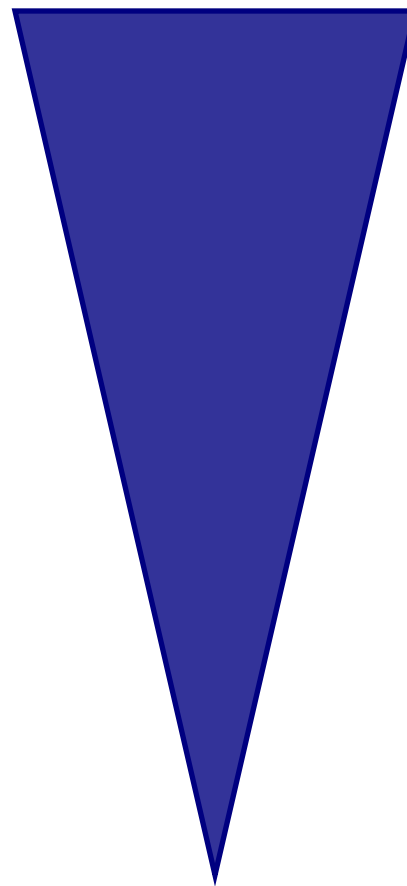
Release of RFA, RFP, etc.

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# Organizational Factors That Affect Program Priorities

- Planning
- People
- Support
- Time
  - Processes slow . . .
  - Risk of getting “lapped” . . .
- Serendipity
  - NIH budget health . . .
  - Competing initiatives . . .
  - Weather . . .

Amount of control



# Planning

- Professional society recommendations
- NIH-sponsored workshops
- NIH advisory groups (Board of External Experts, NHLB Advisory Council)

# Exploratory/Developmental (R21) Bioengineering Research Grants

- The Exploratory/Developmental Bioengineering Research Grants (EBRG) [R21] program announcement encourages innovation and high risk/impact bioengineering research in new areas
- Funding is for 2 years, with up to \$275,000 direct costs over the 2 year period
- <http://grants.nih.gov/grants/guide/pa-files/PA-10-010.html>



# Bioengineering Research Grants (R01)

- The Bioengineering Research Grants (BRG) [R01] program announcement supports basic and applied multi-disciplinary research that addresses important biological, bioengineering or medical research problems
- Funding is for up to 5 years, and generally is less than \$500K direct costs per year
- Usually supports a single laboratory or a small number of investigators
- <http://grants.nih.gov/grants/guide/pa-files/PA-10-009.html>

# Bioengineering Research Partnerships (BRP) [R01]

- The Bioengineering Research Partnerships (BRP) [R01] program announcement supports basic, applied, and translational multi-disciplinary research that addresses important biological or medical research problems
- Funding is for up to 5 years; NHLBI caps applications at \$1 million direct costs per year, while other institutes may allow up to \$2 million direct costs per year
- Supports partnerships between 2 or more groups; industrial participation encouraged
- The current announcement expires in May 2010, but a renewal is anticipated
- <http://grants.nih.gov/grants/guide/pa-files/PAR-07-352.html>

# Small Business Support

- NIH supports research and development at small businesses through the SBIR and STTR programs
- SBIR grants are focused more directly on small businesses, while STTR grants support technology transfer from academic institutions to small businesses
- Phase I grants are typically for \$100K for 6 months, while Phase II grants are typically for up to \$750K per year for 2 years (these are guidelines, not caps)
- Grants can support anything from technology development through clinical trials
- <http://grants.nih.gov/grants/funding/sbir.htm>

# Small Business Support

- NHLBI also supports Phase II SBIR Competing Continuation grants designed to support research required to obtain FDA clearance or approval
- Budgets up to \$1 million total costs per year for up to 3 years may be requested

# Ancillary Studies in Clinical Trials (R01)

- The Ancillary Studies in Clinical Trials (R01) RFA program announcement supports research grant applications to conduct time-sensitive ancillary studies related to heart, lung, and blood diseases and sleep disorders in conjunction with ongoing NIH- or non-NIH-supported clinical trials.
- Funding is for up to 4 years; NHLBI caps applications at \$250K in direct costs per year.
- Example: Imaging studies to elucidate disease progression or mechanism of action of the intervention
- The current announcement expired in October 2009, but a renewal is in progress
- <http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-09-001.html>

# Cohort Studies

- Reading Centers and Leaders in NHLBI Translational Imaging Research
  - ARIC
  - MESA
  - CARDIA: Speckle Tracking Echocardiography
  - Jackson Heart Study

# Comparative Effectiveness Research, Another Area Ripe for Clinical Imaging Research

**CER is “...a rigorous evaluation of the impact of different options that are available for treating a given medical condition, for a particular set of patients.”**

- ...may compare similar treatments, such as competing drugs-- or analyze different approaches, such as surgery vs. drug
- ...may focus only on the relative medical risks and benefits-- or may weigh both costs and benefits”

# Why Should CER be a Priority?

—“Only a *limited amount of evidence is available* about which treatments work best for which patients and whether the added benefits of more-effective but more-expensive services are sufficient to warrant their added costs—yet current practice tends to adopt more-expensive treatments *even in the absence of rigorous assessments* of their impacts....”



Peter Orszag



# Is This So?

## Scientific Evidence Underlying the ACC/AHA Clinical Practice Guidelines

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Pierluigi Tricoci, MD, MHS, PhD

---

Joseph M. Allen, MA

---

Judith M. Kramer, MD, MS

---

Robert M. Califf, MD

---

Sidney C. Smith Jr, MD

---

**C**LINICAL PRACTICE GUIDELINES are systematically developed statements to assist practitioners with decisions about appropriate health care for spe-

**Context** The joint cardiovascular practice guidelines of the American College of Cardiology (ACC) and the American Heart Association (AHA) have become important documents for guiding cardiology practice and establishing benchmarks for quality of care.

**Objective** To describe the evolution of recommendations in ACC/AHA cardiovascular guidelines and the distribution of recommendations across classes of recommendations and levels of evidence.

**Data Sources and Study Selection** Data from all ACC/AHA practice guidelines issued from 1984 to September 2008 were abstracted by personnel in the ACC Science and Quality Division. Fifty-three guidelines on 22 topics, including a total of 7196 recommendations, were abstracted.

Nearly 50% of recommendations are based on expert opinion.  
Only 11% are based on multiple randomized trials.

# Review

- NHLBI
  - Contracts
  - RFAs
  - Some PAs
  - >\$500K Multi-site clinical trials or epidemiologic studies
- CSR
  - Surgical Sciences, Biomedical Imaging and Bioengineering (SBIB)
    - Medical Imaging Study Section (MEDI)
  - Population Sciences and Epidemiology (PSE)

# New Scoring System

- 5 Core Criteria
  - Significance
  - Investigator(s)
  - Innovation
  - Approach
  - Environment
- <http://grants.nih.gov/grants/guide/noticefile/NOT-OD-09-024.html>
- Uses a 9-point scale (1 =exceptional, 9 = poor) for both overall impact/priority scores and for individual criterion scores

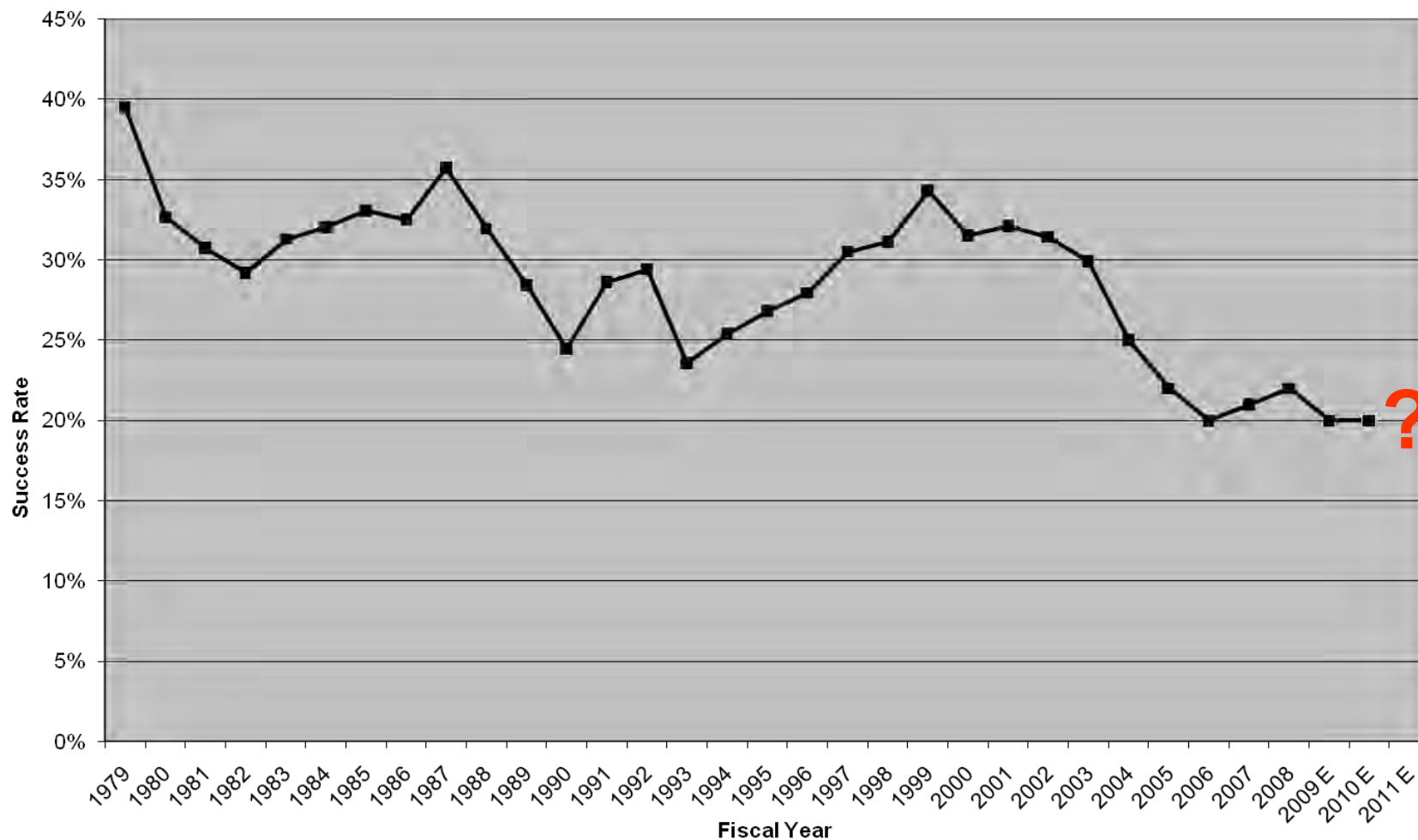
# Overall Impact/Priority Score

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

# Criterion Scores

Criterion	Score	Descriptor	Strengths/Weaknesses
Significance, Investigator(s), Innovation, Approach, Environment	1	Exceptional	
	2	Outstanding	
	3	Excellent	
	4	Very Good	
	5	Good	
	6	Satisfactory	
	7	Fair	
	8	Marginal	
	9	Poor	

# NIH Success Rates (1979-2010)



# NHLBI R01 Payline for FY 2010

Amendment Status	Percentile
A0	16.0
A1	12.0
A2	10.0

<http://www.nhlbi.nih.gov/funding/policies/operguid.htm>

# NHLBI Specific Success Rates

Activity	# Applications Reviewed	# Applications Awarded	Success Rate
Research Projects	4,492	999	22.2%
Training and Research Education	1,269	471	37.1%
Totals	5,761	1,470	25.5%



# Communication

Journal of the American College of Cardiology  
© 2009 by the American College of Cardiology Foundation  
Published by Elsevier Inc.

Vol. 53, No. 12, 2009  
ISSN 0735-1097/09/\$36.00  
doi:10.1016/j.jacc.2009.01.010

## News from the NHLBI

### The Cardiovascular Programs of the National Heart, Lung, and Blood Institute: From Vision to Action to Impact

Elizabeth G. Nabel, MD, Michael S. Lauer, MD

Journal of the American College of Cardiology  
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Published by Elsevier Inc.

Vol. 53, No. 12, 2009  
ISSN 0735-1097/09/\$36.00  
doi:10.1016/j.jacc.2008.11.047

## News from the NHLBI

### Comparative Effectiveness Research: The View From the NHLBI

Michael S. Lauer, MD

Nabel E and Lauer M. JACC 2009;53:1082-6



# RePORT: report.nih.gov

The screenshot shows the NIH Research Portfolio Online Reporting Tools (RePORT) website. The browser window title is "NIH Research Portfolio Online Reporting Tools (RePORT) - Microsoft Internet Explorer". The address bar shows "http://report.nih.gov/index.aspx". The website header includes the U.S. Department of Health & Human Services logo and the text "NATIONAL INSTITUTES OF HEALTH Research Portfolio Online Reporting Tools (RePORT) REPORTS, DATA AND ANALYSES OF NIH RESEARCH ACTIVITIES". A search bar is located in the top right corner. Below the header is a navigation menu with links: FREQUENTLY REQUESTED REPORTS, REPORTS, CATEGORICAL SPENDING, RePORTER, GLOSSARY, FAQs, LINKS, and CONTACT US. The main content area features a "NEWS UPDATES" section on the left, a "NIH DATA BOOK" section in the center, and a grid of nine icons representing various data categories: Strategic Plans, Budget & Spending, Success Rates, Categorical Spending, Funded Organizations, Investigators and Trainees, NIH Data Book, Special Reports Biennial Report, and Searchable Public Databases Reports Search. A sidebar on the left contains quick links for RePORTER, RECOVERY ACT, NIH RECOVERY ACT INVESTMENT REPORTS, RePORT TUTORIAL, RePORT BROCHURE, BIENNIAL REPORT OF THE DIRECTOR, CATEGORICAL SPENDING, NIH Data Book, and Award Data for Individual Organizations.

# Contact Information

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