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
Division of Cardiovascular Sciences

Michael Lauer, MD
Office of the Director

- Office of Biostatistics Research (HNH92)
- Office of Special Projects (HNH93)
- Office of Research Training and Career Development (HNH94)
- Program in Basic & Early Translational Research (HNH95)
  - Advanced Technologies and Surgery Branch (HNH952)
  - Vascular Biology and Hypertension Branch (HNH953)
- Program in Adult & Pediatric Cardiac Research (HNH96)
  - Heart Development and Structural Disease Branch (HNH962)
  - Atherothrombosis & Coronary Artery Disease Branch (HNH963)
  - Heart Failure and Arrhythmias Branch (HNH964)
- Program in Prevention and Population Sciences (HNH97)
  - Clinical Applications & Prevention Branch (HNH972)
  - Epidemiology Branch (HNH973)
  - Women’s Health Initiative (HNH974)
NIH Extramural & Intramural Funding
FY 2010 Final Budget: $30.988 Billion*

Spending at NIH
$5.0 B
16%
- $3.2 B Intramural Research
- $1.7 B Research Management & Support
- $0.1 B Buildings and Facilities

Spending Outside NIH
$26.0 B
84%
- Supports over 325,000 Scientists & Research Personnel
- Supports over 3,000 Institutions

* Includes $150 million from the Special type 1 Diabetes appropriation.
NIH Funding Distribution by Mechanism
FY 2010 Budget $30.988 Billion

Research Project Grants $16,382 52.9%
Research Centers 9.9%
Other Research 6.0%
Research Training 2.6%
R&D Contracts 11.0%
Intramural Research 10.4%
Res. Mgmt. & Support 4.6%
All Other 2.7%
# NHLBI Non-ARRA Budget – FY 2009
(Dollars in Thousands)

<table>
<thead>
<tr>
<th>Category</th>
<th>FY 2009 Actual</th>
</tr>
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<tbody>
<tr>
<td>Res. Project Grants:</td>
<td></td>
</tr>
<tr>
<td>Noncompeting &amp; Competing</td>
<td>$1,959,738</td>
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<tr>
<td><strong>Subtotal</strong></td>
<td><strong>$1,959,738</strong></td>
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<tr>
<td>SBIR/STTR</td>
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<td><strong>Subtotal, RPGs</strong></td>
<td><strong>$2,036,138</strong></td>
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<td>Research Centers, Careers, Other</td>
<td>221,154</td>
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<tr>
<td>Research Training</td>
<td>96,579</td>
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<td>Research Contracts</td>
<td>366,010</td>
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<td><strong>Total, Extramural</strong></td>
<td><strong>$2,719,881</strong></td>
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<td>Intramural Research</td>
<td>181,737</td>
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<tr>
<td>Res. Mgmt &amp; Support</td>
<td>114,071</td>
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<td><strong>Total, NHLBI</strong></td>
<td><strong>$3,015,689</strong></td>
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### Number of Research Grants and Training Positions FY 2009

<table>
<thead>
<tr>
<th>FY 2009</th>
<th>Actual</th>
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<tr>
<td><strong>Research Grants</strong></td>
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<tr>
<td>Noncompeting</td>
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<td>Competing</td>
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<td>SBIR/STTR</td>
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<td><strong>Subtotal, RPGs</strong></td>
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<tr>
<td>Research Centers</td>
<td>43</td>
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<tr>
<td>Research Careers</td>
<td>572</td>
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<tr>
<td>Other Research</td>
<td>144</td>
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<tr>
<td><strong>Total, Res. Grants</strong></td>
<td>4,820</td>
</tr>
</tbody>
</table>

| **Full Time Training Positions** | |
| Research Training | 1,989 |
| Research Contracts | 216 |
Recession: Global, National, and Local


IMF Chief Says Nations in 'Depression'

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 official figure, and were far more pessimistic than forecasts released by the IMF as recently as 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 deeply. 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 advisor 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

U.S. Loses 533,000 Jobs in November

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 fibrosis 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

- Short-Term Training Grant (T35)
- Institutional Training Grants (T32)
- Postdoctoral Fellowships (F32)
- Senior Fellowships (F33)

Medical School

Internship/Residency

Specialty

- Scientist Development Program (K12)
- Mentored Clinical Scientist Development Award (K08)
- NIH Pathway to Independence (PI) Award (K99/R00)
- Mentored Patient-Oriented Research CDA (K23)

Independent Investigator

- Career Enhancement Award Stem Cells (K18)
- Midcareer Investigator in Patient-Oriented Research (K24)
# Spectrum of Research Training & Career Development Awards

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

Program Length:
- 2-3 years
- 3-5 years
How NHLBI Establishes Scientific Priorities

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

Other Factors

<table>
<thead>
<tr>
<th>Feasibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Innovation</td>
</tr>
<tr>
<td>Likelihood that entity outside Institute would support</td>
</tr>
<tr>
<td>Multidisciplinary Nature</td>
</tr>
<tr>
<td>Potential impact on individual health</td>
</tr>
<tr>
<td>Potential impact on national health care expenditures</td>
</tr>
<tr>
<td>Potential impact on population health</td>
</tr>
<tr>
<td>Qualifications and track record of the proposer</td>
</tr>
<tr>
<td>Quality of proposed methods</td>
</tr>
<tr>
<td>Quality of writing and organization of proposal</td>
</tr>
<tr>
<td>Relevance to global agenda</td>
</tr>
<tr>
<td>Relevance to mission and strategic plan</td>
</tr>
<tr>
<td>Research need/Lack of studies</td>
</tr>
<tr>
<td>Study cost</td>
</tr>
<tr>
<td>Uniqueness or timeliness of opportunity</td>
</tr>
</tbody>
</table>
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.
Organizational Factors That Affect Program Priorities

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

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

See the official announcement [here](http://grants.nih.gov/grants/guide/pa-files/PA-10-009.html).
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.

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](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
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.
Cohort Studies

- Reading Centers and Leaders in NHLBI Translational Imaging Research
  - ARIC
  - MESA
  - CARDIA: Speckle Tracking Echocardiography
  - Jackson Heart Study
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
Scientific Evidence Underlying the ACC/AHA Clinical Practice Guidelines

Pierluigi Tricoci, MD, MHS, PhD
Joseph M. Allen, MA
Judith M. Kramer, MD, MS
Robert M. Califf, MD
Sidney C. Smith Jr, MD

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


• Uses a 9-point scale (1 = exceptional, 9 = poor) for both overall impact/priority scores and for individual criterion scores
# Overall Impact/Priority Score

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<tr>
<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
<th>Strengths/Weaknesses</th>
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<tr>
<td><strong>High Impact</strong></td>
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<tr>
<td></td>
<td>1</td>
<td>Exceptional</td>
<td>Strengths</td>
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<td></td>
<td>2</td>
<td>Outstanding</td>
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<td></td>
<td>3</td>
<td>Excellent</td>
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<tr>
<td><strong>Moderate Impact</strong></td>
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<td></td>
<td>4</td>
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<td></td>
<td>5</td>
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<td></td>
<td>6</td>
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<td><strong>Low Impact</strong></td>
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<td></td>
<td>7</td>
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<td>Weaknesses</td>
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<td></td>
<td>8</td>
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<tr>
<td></td>
<td>9</td>
<td>Poor</td>
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## Criterion Scores

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<tr>
<th>Criterion</th>
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<tr>
<td>Significance, Investigator(s), Innovation, Approach, Environment</td>
<td>1</td>
<td>Exceptional</td>
<td>Strengths</td>
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<td></td>
<td>2</td>
<td>Outstanding</td>
<td></td>
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<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>Very Good</td>
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<td>5</td>
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<tr>
<td></td>
<td>9</td>
<td>Poor</td>
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</table>

The table above outlines the criterion scores and their corresponding descriptors. The scores range from 1 (Exceptional) to 9 (Poor), indicating the strengths and weaknesses in various aspects such as significance, investigator(s), innovation, approach, and environment. The right side of the table separates strengths from weaknesses.
NIH Success Rates (1979-2010)

Success Rates 1979 – 2003
Achieved 30% in 16 of 25 years (64%)
Achieved 25% in 23 of 25 years (92%)

Optimal Success Rate = 30%
# NHLBI R01 Payline for FY 2010

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<th>Amendment Status</th>
<th>Percentile</th>
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<tr>
<td>A1</td>
<td>12.0</td>
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<tr>
<td>A2</td>
<td>10.0</td>
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</table>

### NHLBI Specific Success Rates

<table>
<thead>
<tr>
<th>Activity</th>
<th># Applications Reviewed</th>
<th># Applications Awarded</th>
<th>Success Rate</th>
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<tbody>
<tr>
<td>Research Projects</td>
<td>4,492</td>
<td>999</td>
<td>22.2%</td>
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<tr>
<td>Training and Research Education</td>
<td>1,269</td>
<td>471</td>
<td>37.1%</td>
</tr>
<tr>
<td>Totals</td>
<td>5,761</td>
<td>1,470</td>
<td>25.5%</td>
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Communication

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

Comparative Effectiveness Research: The View From the NHLBI

Michael S. Lauer, MD
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