The NIH-Wide Strategic Plan FYs 2021-2025

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FDP MEETING, SEPTEMBER 20, 2021

National Institutes of Health
Division of Program Coordination, Planning, and Strategic Initiatives

The NIH-Wide Strategic Plan

- How does NIH develop and communicate strategies by which it pursues its mission and goals?
- How does NIH set its goals?
- How does NIH know that it is making progress towards achieving its goals?

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Developing the NIH-Wide Strategic Plan for FYs 2021-2025

JAMES M. ANDERSON, MD PHD

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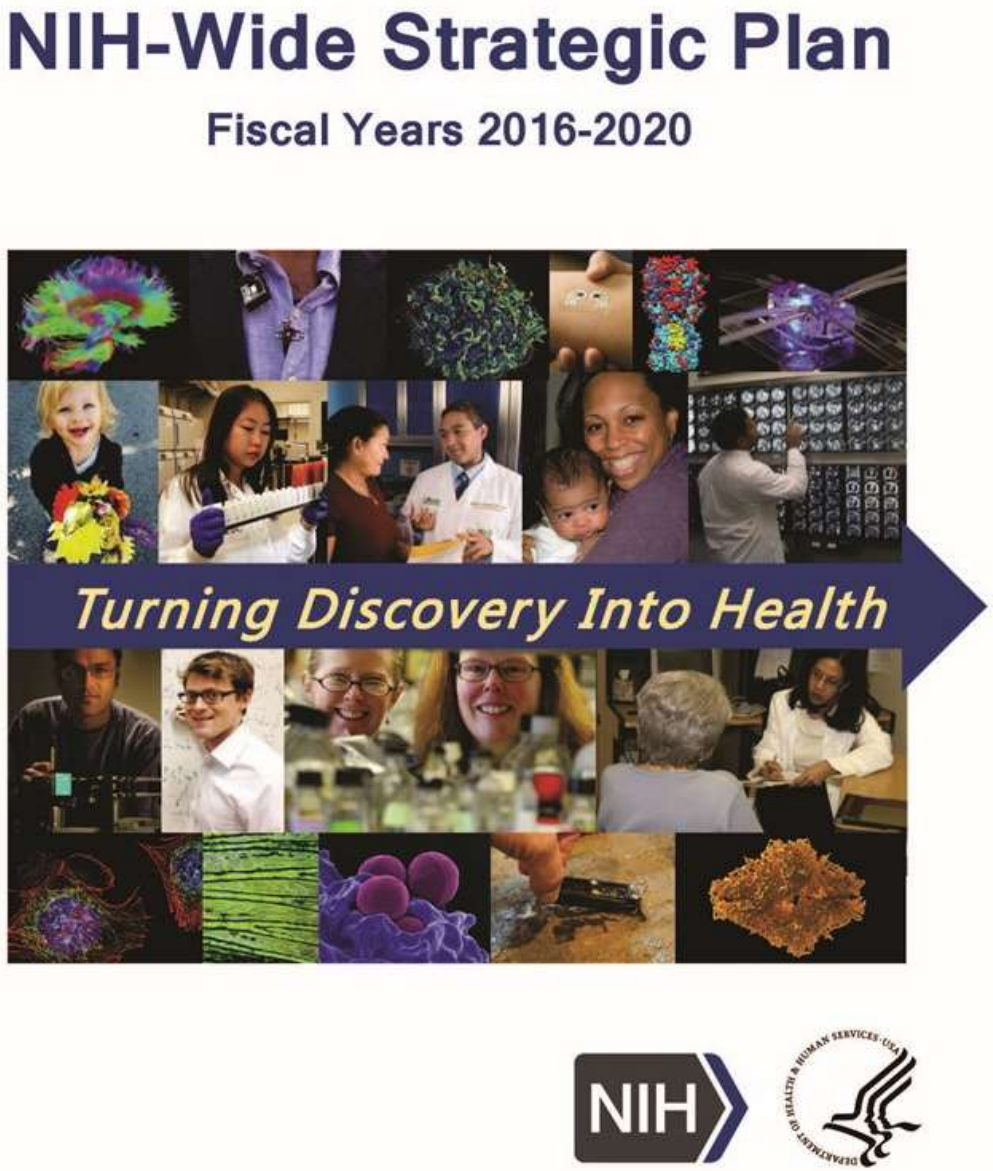
NIH-Wide Strategic Plan for FYs 2016-2020



21st Century Cures Act

- **P.L. 114-255**
  - Signed into law Dec 13, 2016
- **Requirements**
  - NIH-Wide Strategic Plan to be developed a minimum of every 6 years
  - IC strategic plans to be informed by the NIH-Wide Strategic Plan
  - Use of a Common Template to harmonize strategic plans across NIH
  - Others

Goals of the NIH-Wide Strategic Plan

The Plan:

- Clearly articulates the highest priorities of the NIH overall
- Describes how the NIH will achieve the highest priorities
- Represents an update on the last Plan – including accomplishments under last plan and new initiatives across NIH

The Plan **DOES NOT**:

- Describe all the many important things that NIH does and will do in the future
- Address priorities of the individual Institutes, Centers, and Offices (ICOs) since each of the ICOs has their own strategic plan
- Be a complete overhaul of the last Plan

Development of the NIH-Wide Strategic Plan

Sep 2019 – Jan 2020

Phase 1: NIH Input & Develop Strategic Plan Framework

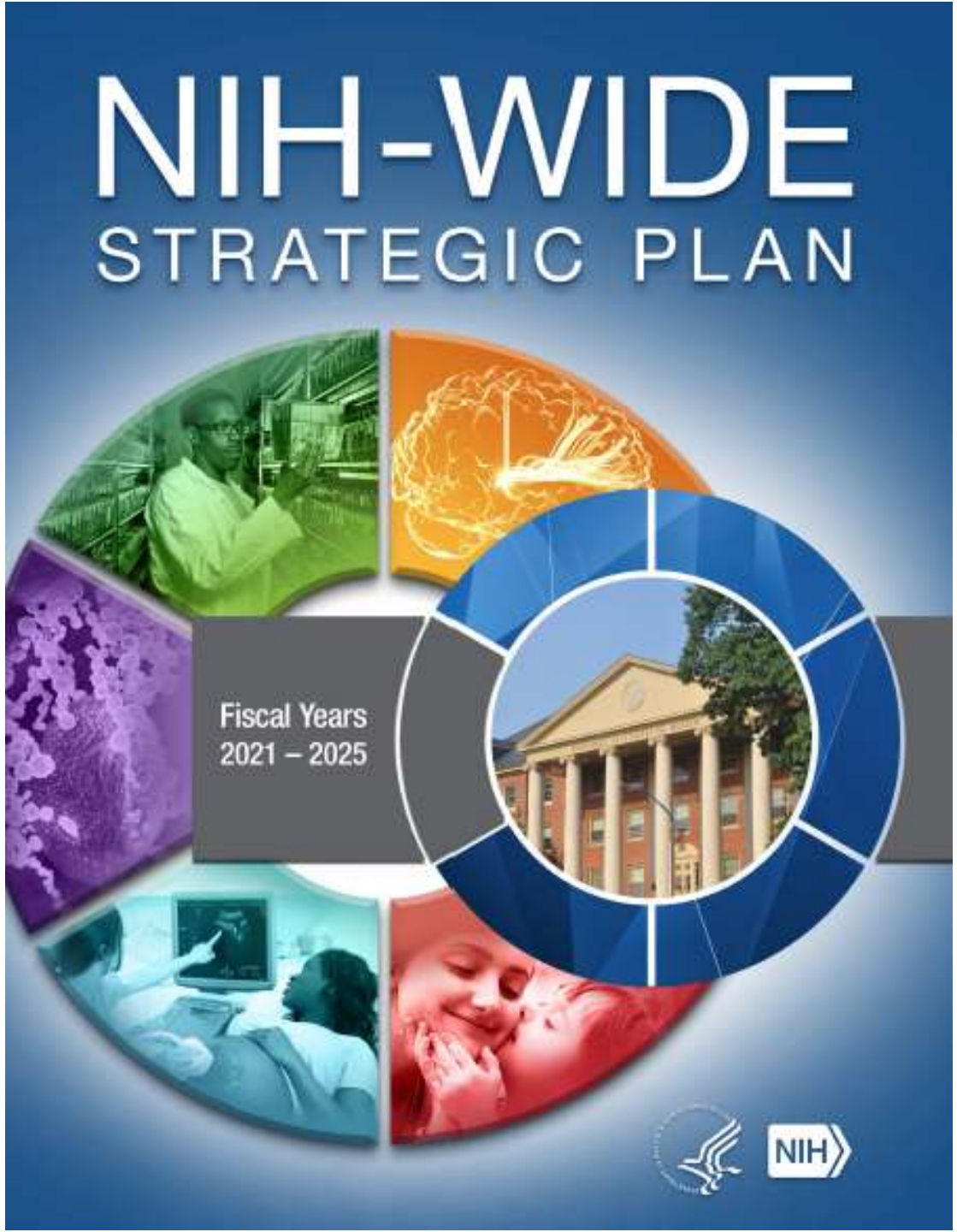
Jan 2020 – July 2020

Phase 2: Public Input & Draft Strategic Plan

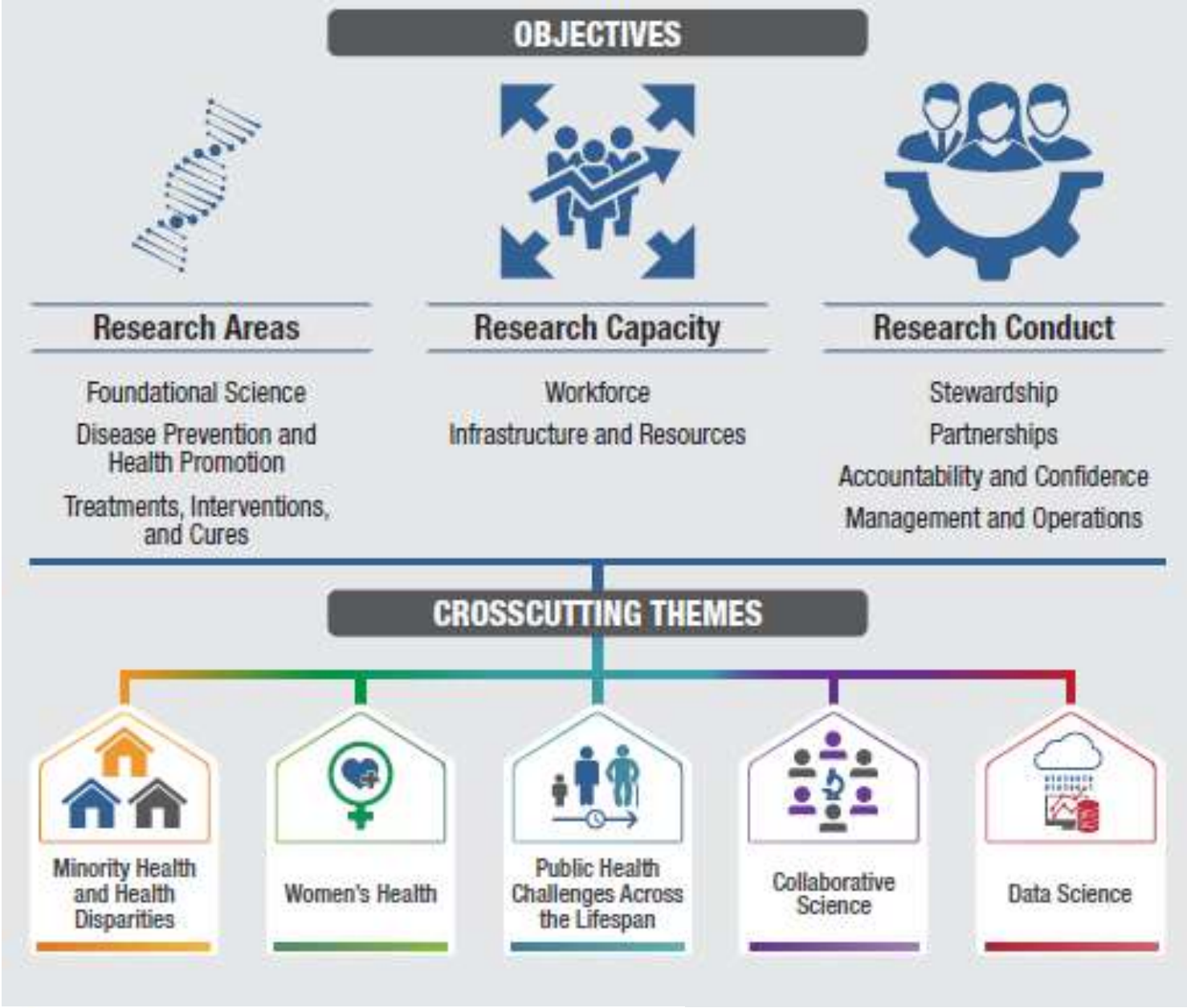
July 2020 – July 2021

Phase 3: Approval Process

Released on July 31, 2021



Strategic Plan Framework



Objective 1: Advancing Biomedical and Behavioral Sciences

HIGHLIGHTED CONTENT

Driving Foundational Science:
BRAIN Initiative®

The Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative® aims to revolutionize our understanding of the human brain by accelerating the development of new technologies. The goals are to:

- Map the brain's cell types and their connections;
- Develop tools to monitor, modulate and analyze complex patterns of circuit activity that give rise to our thoughts and behaviors - in health and disease;
- Restore circuit function to treat brain diseases.

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Preventing Disease and Promoting Health: Universal Flu Vaccine

NIH is sponsoring a trial of a universal flu vaccine candidate using nanoparticle technology to display portions of the influenza virus that are the same or very similar among different influenza strains.

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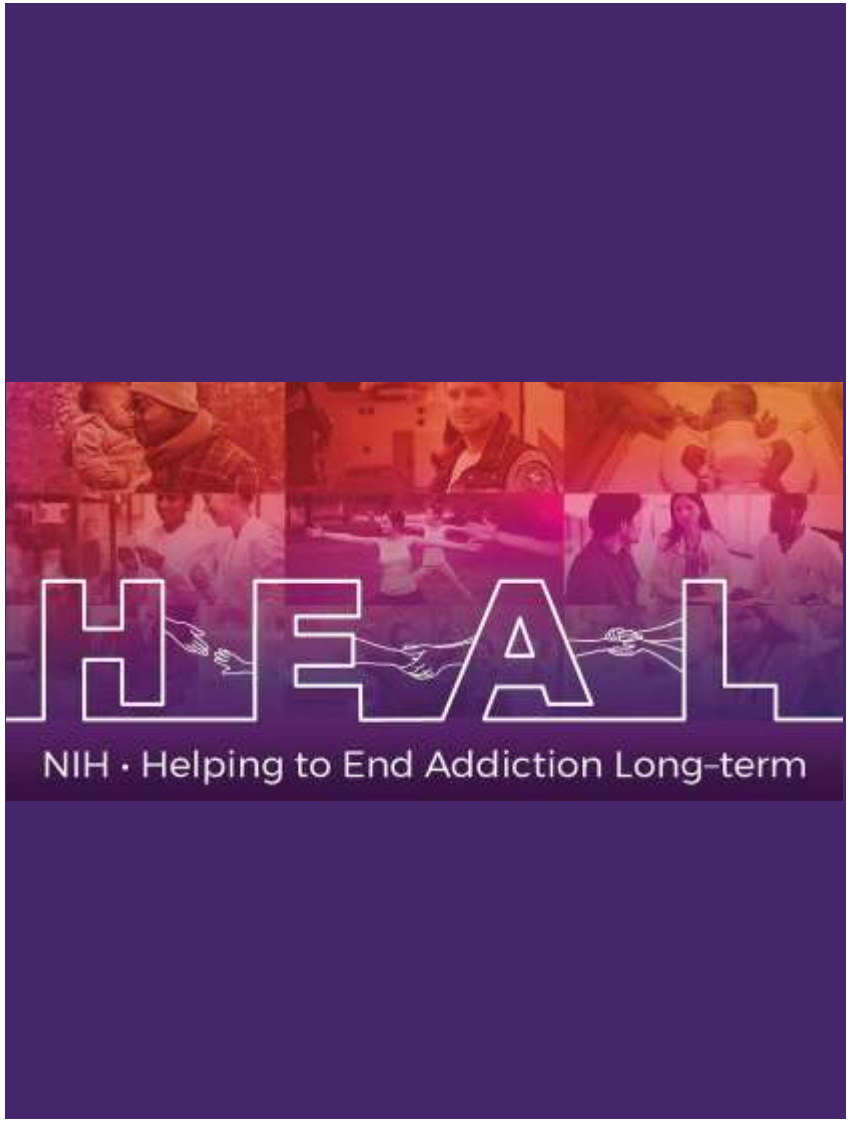

Developing Treatments, Interventions, and Cures: HEAL Initiative℠

Launched in April 2018, the NIH HEAL (Helping to End Addiction Long-term) Initiative℠ is an aggressive, NIH-wide effort to speed scientific solutions to stem the national opioid public health crisis.

NIH has built a data repository to maximize publication availability and data sharing for NIH HEAL Initiative℠ research projects.

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Objective 2: Developing, Maintaining, and Renewing Scientific Research Capacity

HIGHLIGHTED CONTENT

Enhancing the Biomedical Research Workforce: Native American Research Internship Program (NARI)

The NARI program supports American Indian and Alaska Native undergraduates from across the country in paid summer research internships at the University of Utah.

Since its inception, the program has supported 128 students from 65 tribal nations.

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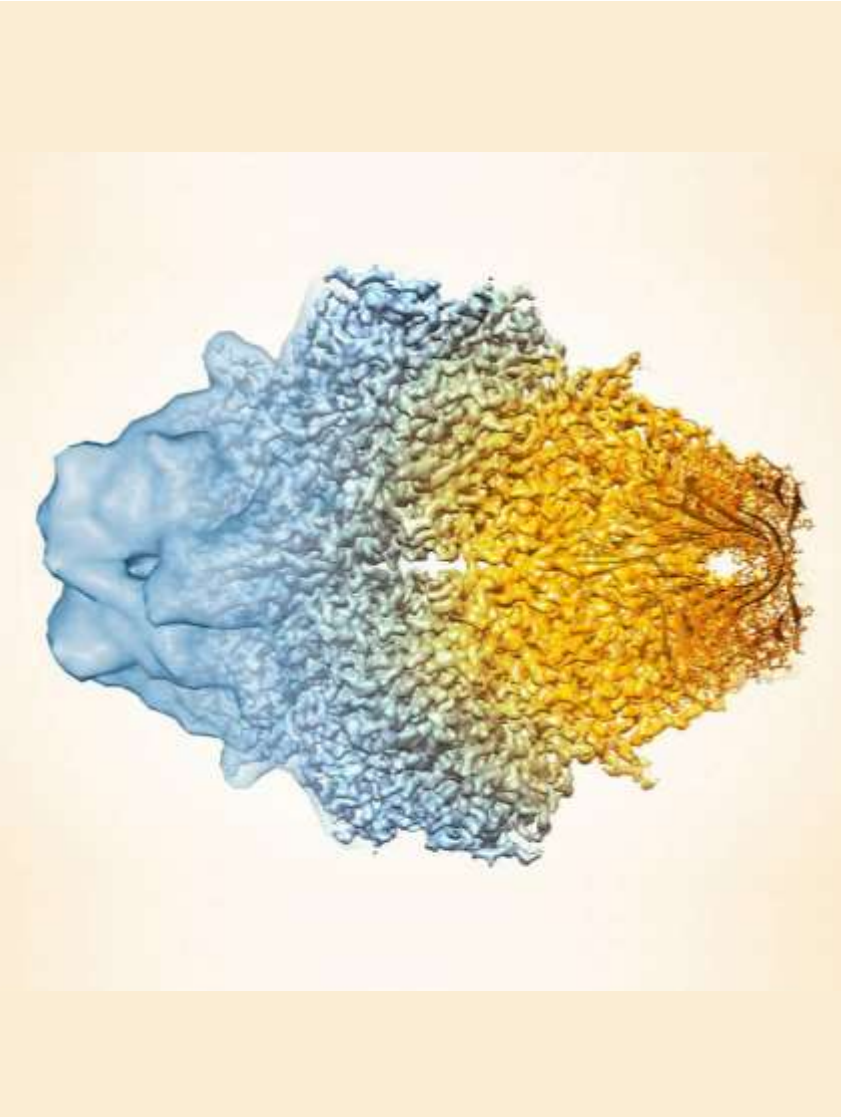

Supporting Research Resources and Infrastructure: Transformative High Resolution Cryo-EM Program

Launched in 2018, some centers have already begun to offer use of Cryo-EM.

In 2021, this program plans to launch an additional effort to increase access to cryo-electron tomography, a related technology that enables improved imaging of molecules within intact cells and tissues in three dimensions.

Objective 3: Exemplifying and Promoting the Highest Level of Scientific Integrity, Public Accountability, and Social Responsibility in the Conduct of Science

HIGHLIGHTED CONTENT

Fostering a Culture of Good Scientific Stewardship: New PubMed Central

In 2020, NIH launched the new PubMed.

The most heavily used biomedical literature citation database in the world, which enables the communication and discovery of scientific literature around the world.

NIH's PubMed Central (PMC) provides public access to the full text of more than 6 million peer-reviewed research articles

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Leveraging Partnerships: ACTIV

To hasten the development of interventions for COVID-19, NIH is leading the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership.

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Ensuring Accountability and Confidence in Biomedical and Behavioral Sciences: Anti-Harassment

NIH has started a campaign to create a safe and civil workplace wherever NIH-funded research is conducted.

NIH issued several new policies, guidelines, and requirements on this topic and communicated them widely to make expectations clear to NIH-funded organizations and the workforce at NIH.

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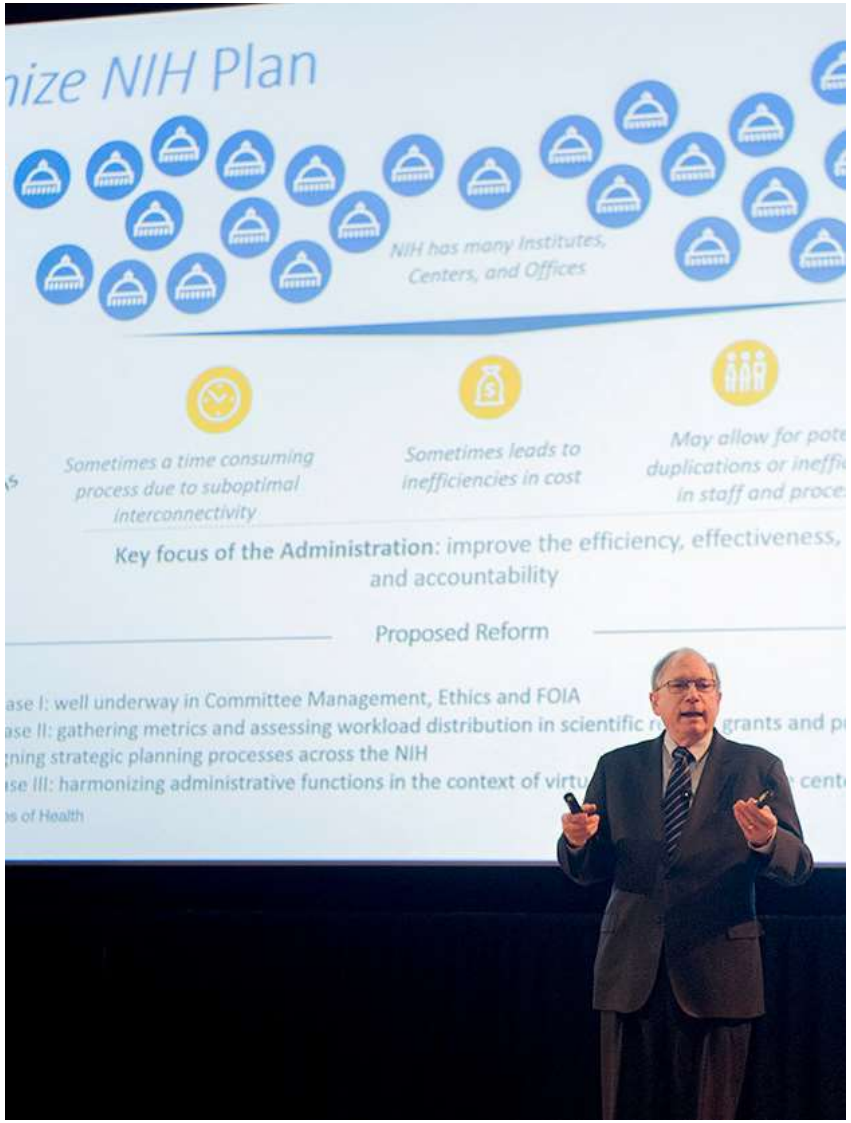

Optimizing Operations: Optimize NIH

Established as part of the *Reimagine HHS* effort to improve performance across the Department's divisions.

Through the Optimize NIH initiative, the agency is focusing on administrative areas that could be made more efficient and effective if managed centrally, or better harmonized across ICs and OD offices.

Bold Predictions

- The regular use of genomic information will have transitioned from boutique to mainstream in all clinical settings, making genomic testing as routine as complete blood counts.
- Research on new approaches to cervical cancer screening will lead to the development of self-sampling for women, with the potential to substantially reduce the incidence and mortality of this disease.
- Infant survival will be optimized by synthesizing milk that captures all of the components and properties of human milk, even individualizing it to the characteristics of the infant's mother.
- NIH-supported researchers will develop a universal coronavirus vaccine.
- The number of NIH R01 awards that support principal investigators from underrepresented racial and ethnic groups will be increased by 50 percent, and the racial funding disparities gap for NIH R01 grants will be eliminated by fiscal year 2025.

- The Stakeholder Communities of the NIH
- The NIH Advisory Committee to the Director
- NIH Council of Councils
- NIH Leadership
- Institute, Center, and Office Directors
- NIH-Wide Strategic Plan Working Group

Thank you to the many contributors

Thank You & Questions

Priority Setting at NIH

SARAH RHODES, PHD

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What is Priority Setting at NIH?

Top Down: Priority Setting

NIH Mission: To seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability.

Bottom Up: Investigator-Initiated

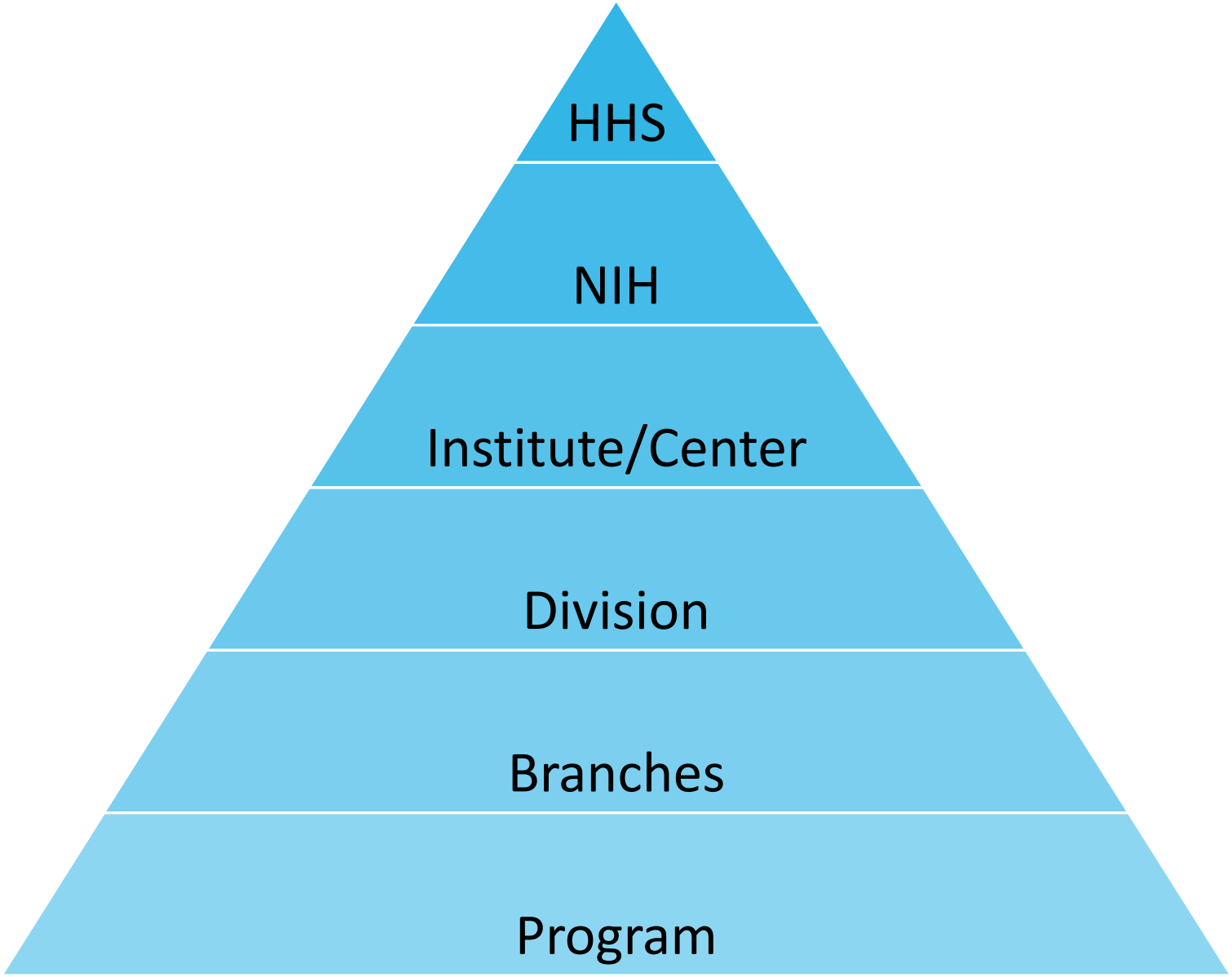
Why is Priority Setting Important?

Good Stewardship!

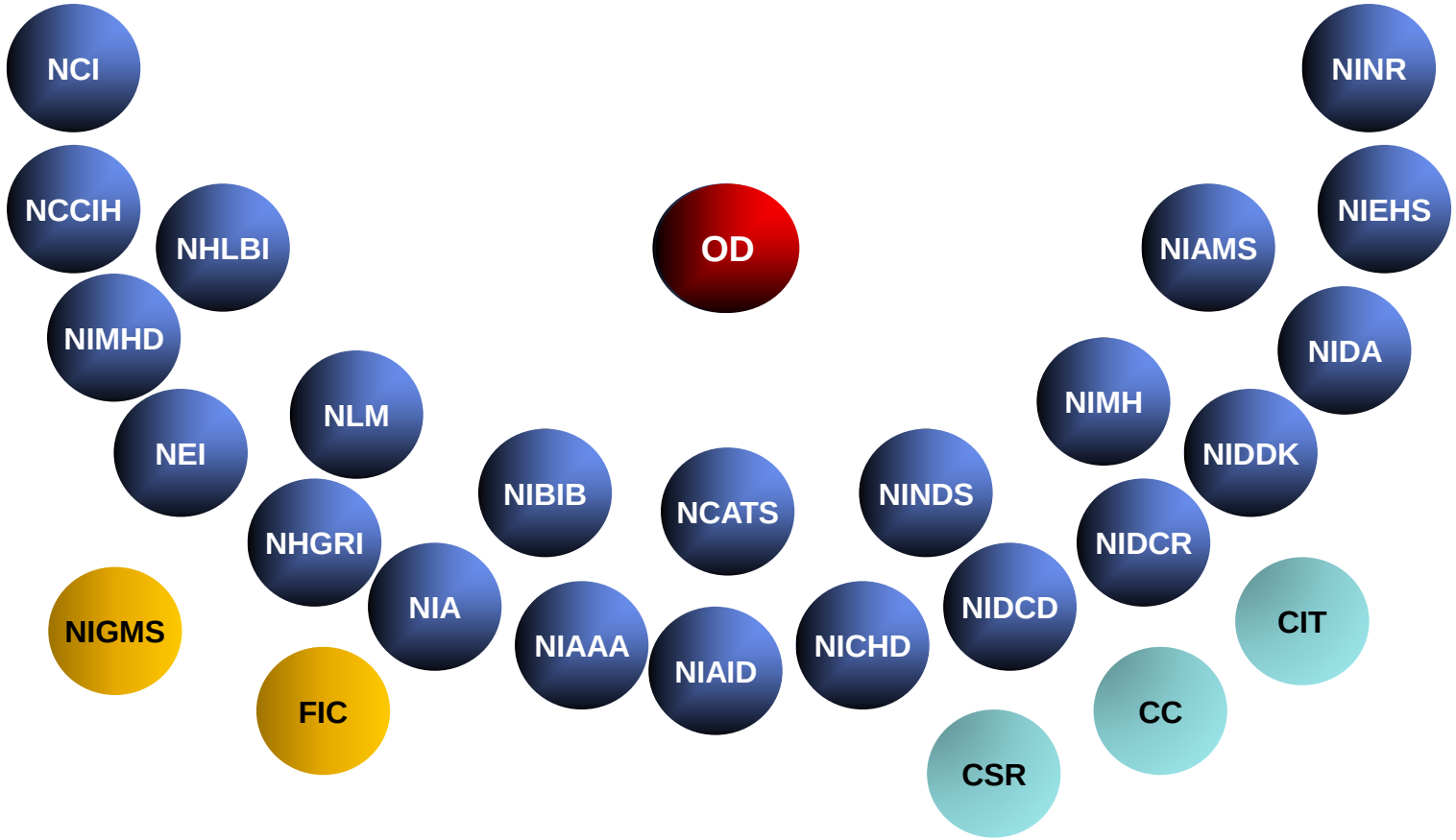
- Largest public funder of biomedical research in the world
- Managing a finite resource
- Responsive to evolving needs and opportunities
- Accountability

What Priorities Does NIH Set?

At What Level Does NIH Set Priorities?



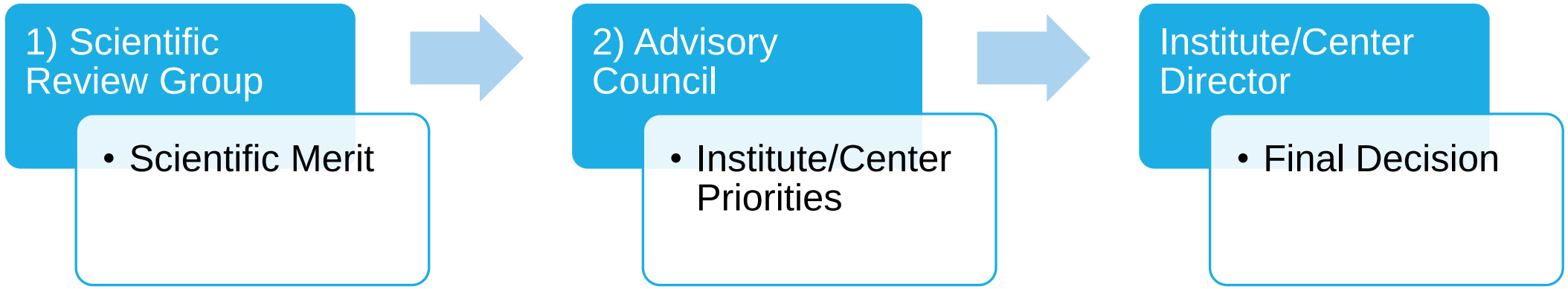
NIH Organization



How do Institutes & Centers Make Funding Decisions?

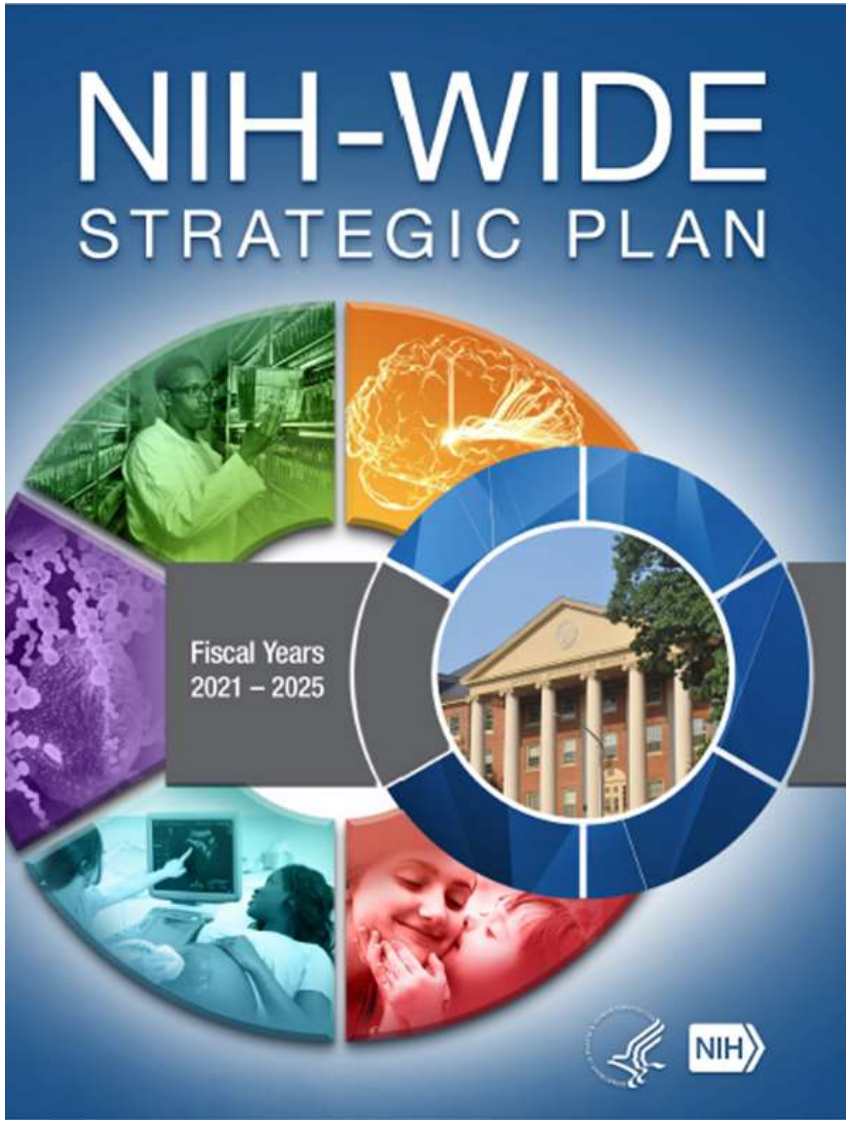
- Categories of Research Funded by NIH
  - Investigator Initiated / Unsolicited / Untargeted
  - Solicited / Targeted

- 2-Stage Peer Review Process



What Factors Inform NIH Priorities?

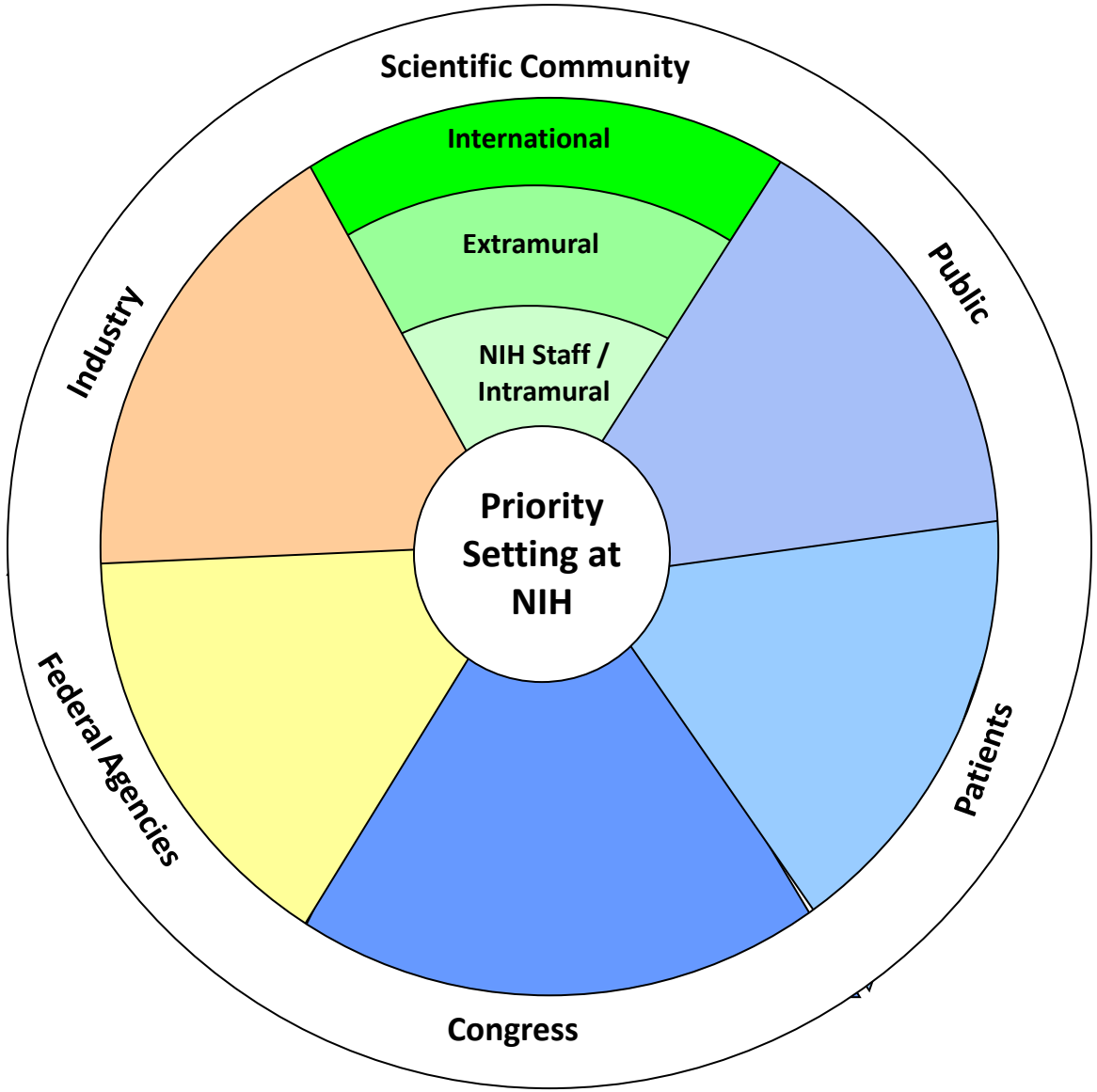
- Mission
- Appropriations
- Scientific Opportunities
- Gaps
- Public Health Needs
- Portfolio Balance
- Other Factors (e.g., Rare Diseases)

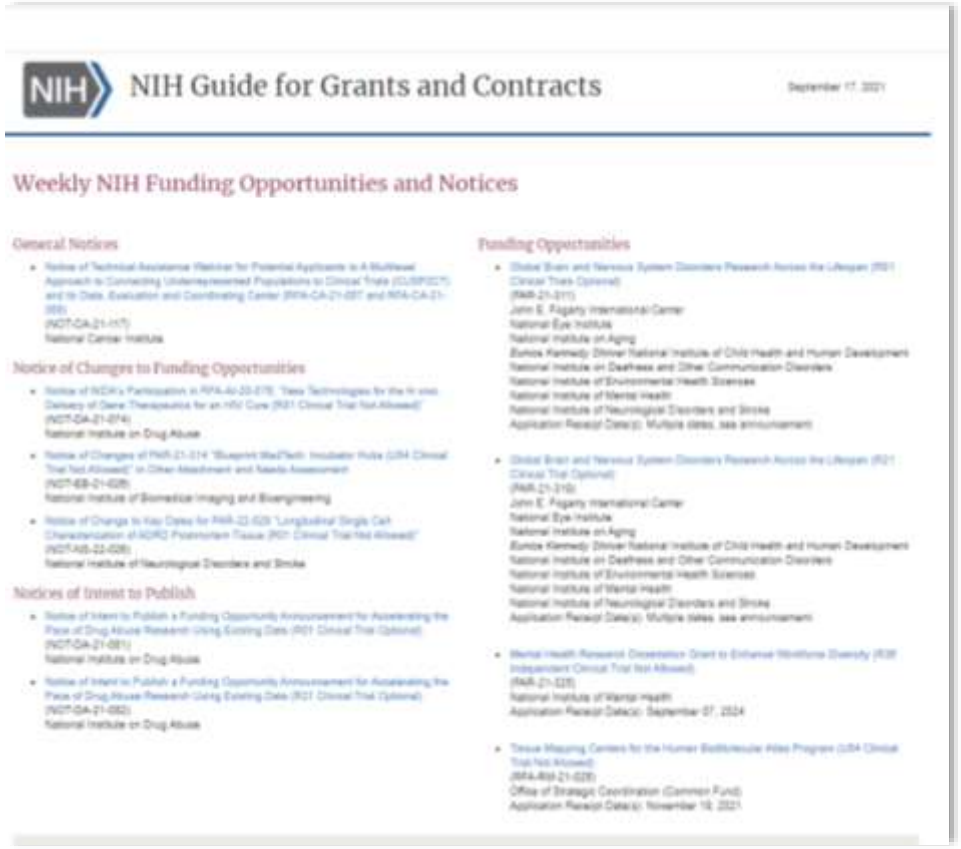


What Priority Setting Approaches Does NIH Use?

- Strategic Planning
- Annual Planning
- Periodic Review

Who Plays a Role in Priority Setting?




NIH Guide for Grants and Contracts

Weekly NIH Funding Opportunities and Notices

General Notices

Notice of Changes to Funding Opportunities

Notices of Intent to Publish

Funding Opportunities

How Does NIH Communicate its Priorities?

- Strategic Plans
- Funding Opportunity Announcements
- Congressional Justification
- Talks

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Thank You & Questions

Measuring Progress at NIH

MARINA VOLKOV, PHD

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Strengthening Stewardship at NIH

- Establishing goals and priorities
- Measuring progress
- Evaluating programs, policies, and operations
- Communicating NIH's value

Reasons to Evaluate

- Responsible stewardship
- Increasing opportunities and expectations
- Improving decision-making

Implementing the Evidence Act

- Establishes processes for the federal government to modernize its data management practices, evidence-building functions, and statistical efficiency to inform policy decisions.
- Title 1: Federal Evidence-Building Activities
  - Agency Evidence-Building Plans
  - Evaluation Plans
  - Evaluation Policy for HHS
  - Capacity Assessment of Evaluation & Evidence-Building Functions
  - Program Evaluation Best Practices and Competencies

NIH's Implementation Activities

- 2-year Evidence Building Plan:
  - Strengthening capacity
- FY22 Evaluation Plans:
  1. Data and tools
  2. Workforce
  3. Leadership's use of and needs for evidence

Reasons to Evaluate NIH Outcomes & Impact

Capturing outcomes is key to evaluation and evidence-gathering activities.

- Responsible stewardship
- Increasing opportunities and expectations
- Improving decision-making

Challenges to Assessing Impact

- Easier to measure generation of knowledge, but difficult to connect to long-range impacts on public health
- NIH produces scientific evidence to improve public health, but is not responsible for implementation
- NIH is not the only funder of biomedical research
- Timelines incredibly long, and value may change with time
- One finding may have implications for numerous outcomes

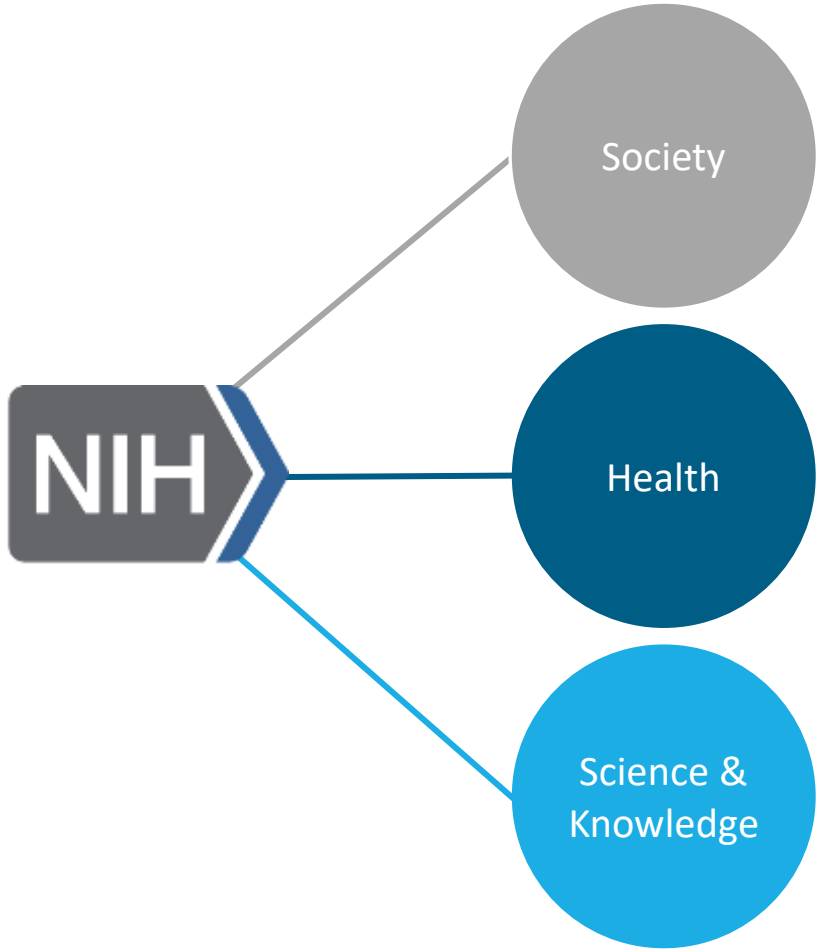
Capturing Outcomes of NIH Research

*Take a more **coordinated** and **systematic** approach to both better **capture** and **communicate** the value of NIH's investments.*

SMRB Recommendations

- Better **capture** NIH's impact
  - Expand the notion of NIH's outcomes and impact (push past publications)
  - Prioritize measuring NIH's impact on health
  - Utilize data-driven approaches to build chains of evidence
- Better **communicate** NIH's impact
  - Provide credible, interpretable, and useful assessments
  - Attribute outcomes to all contributors
- Contribute to a more **coordinated, systematic** approach
  - Coordinate across NIH and work with NIH's many partners and stakeholders
  - Inform development of NIH's data infrastructure and applications for tracking outcomes

Impact of NIH



- Cost savings from improved interventions and health outcomes
- Industry/commercial activity from medical products and technologies
- New businesses/start-ups created

- Number of people treated and/or lives saved
- Quality of life improvements
- FDA approvals, CMS reimbursement determinatons, practice guidelines, health policies, etc.

- Growth/emergence of new fields
- "Spillovers" to other lines of research
- New methodologies and technologies
- Award-winning work (Nobel Prizes, Lasker Awards, *Science's* top discoveries)

Why Case Studies?

- Case studies can:
  - Provide a rigorous way to explain complex pathways of discovery to application
  - Systematically isolate key factors that enable or hinder successful translation
  - Capture a wide variety of impacts, including the unexpected
  - Be used as a tool for research evaluation and science communication
  - Tell a compelling story

RESEARCH-TO-PRACTICE MILESTONES FOR THE Hib VACCINE

For more information on the supporting evidence and research sponsors for these milestones, see the Web appendix.

1920s

By deactivating disease-causing components of bacteria, vaccines were developed to prevent **tetanus and diphtheria.**[14] These advances would later help enhance the effectiveness of Hib vaccines.

1930s

Hib (*seen below right, in photo*) was found to be the primary cause of bacterial meningitis in children. The bacteria could be distinguished under the microscope by their **unique outer coat.**[15] Later, scientists determined this coat was made up of chains of specific **sugar molecules.**[16]

Because sugar chains typically do not stimulate immune responses as well as proteins, researchers began to look for ways to **link the chains to bacterial proteins** in order to enhance their immunogenicity.[17]

1968

The **first attempts at developing a Hib vaccine** focused on the sugar chains – researchers worked on isolating, purifying, and preparing these chains for clinical use.[18] NIH

1970s

NIH-funded clinical trials found that these early **Hib vaccines worked well for children** over age 2, but were not as effective in infants.[19] NIH

1980

FDA scientists (who later moved to NIH) linked Hib sugar chains to immune-stimulating proteins (e.g., from diphtheria), producing a **"conjugate vaccine."**[23] NIH

1983

Scientists leading these clinical trials **founded a company,** called Praxis Biologics (now incorporated into Wyeth), to develop and produce vaccines for children, including Hib vaccines.[20]

1984

NIH and FDA scientists found that this conjugate vaccine triggered immune responses in appropriate **animal models.**[24] NIH

1985

The Food and Drug Administration (FDA) **approved the first Hib vaccines** (including from Praxis Biologics) for use in children two years of age,[21] while researchers explored ways to make the vaccines more effective in infants.[22]

1985–1989

NIH-funded clinical trials showed that the conjugate vaccine was **safe and effective in infants.**[25] NIH

1987–1993

FDA approved the first **4 conjugate vaccines for use in infants.**[26]

1993

The conjugate vaccine developed by NIH-funded scientists was licensed, manufactured, and **commercially distributed.**[27]

CDC included the Hib conjugate vaccine in its **recommended vaccine schedule.**[28]

1995

For their "groundbreaking work and …leadership in the development and commercialization of the [Hib] vaccine," the **Albert and Mary Lasker Foundation** awarded their prestigious Clinical Medical Research Award (often referred to as the "American Nobels") to four NIH-supported scientists.[29] NIH's **National Institute of Allergy and Infectious Diseases** provided grant funding to Drs. Porter Anderson and David Smith. Drs. Rachel Schneerson and John Robbins performed the majority of their research within the intramural laboratories of the ***Eunice Kennedy Shriver*** **National Institute on Child Health and Human Development.**

PROTECTING INFANTS WITH A NEXT-GENERATION CONJUGATE VACCINE

EARLY HIB VACCINE DEVELOPMENT

FOUNDATIONAL RESEARCH

NIH *indicates NIH-funded milestones*

1977: A young girl receives a vaccination, administered by a public health nursing practitioner

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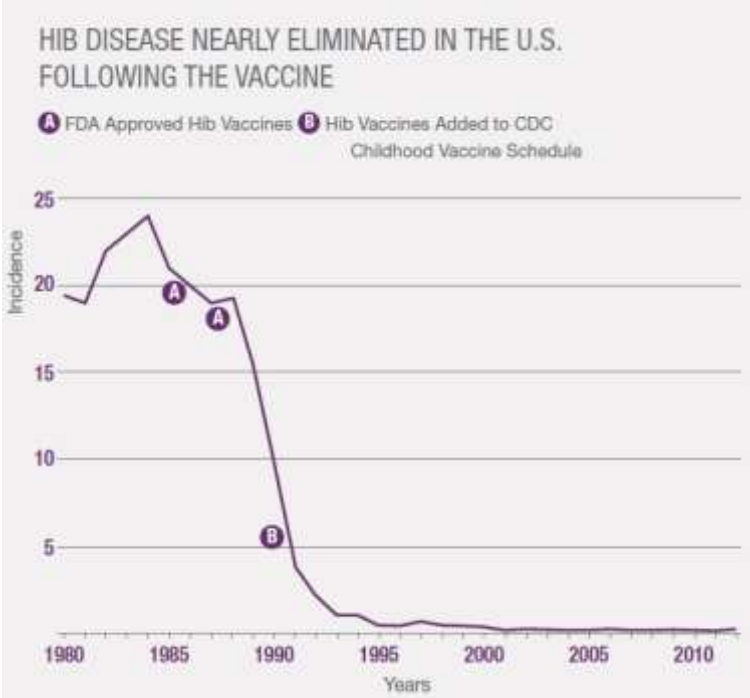
Case Study Example

Hib Vaccine Impact on Health

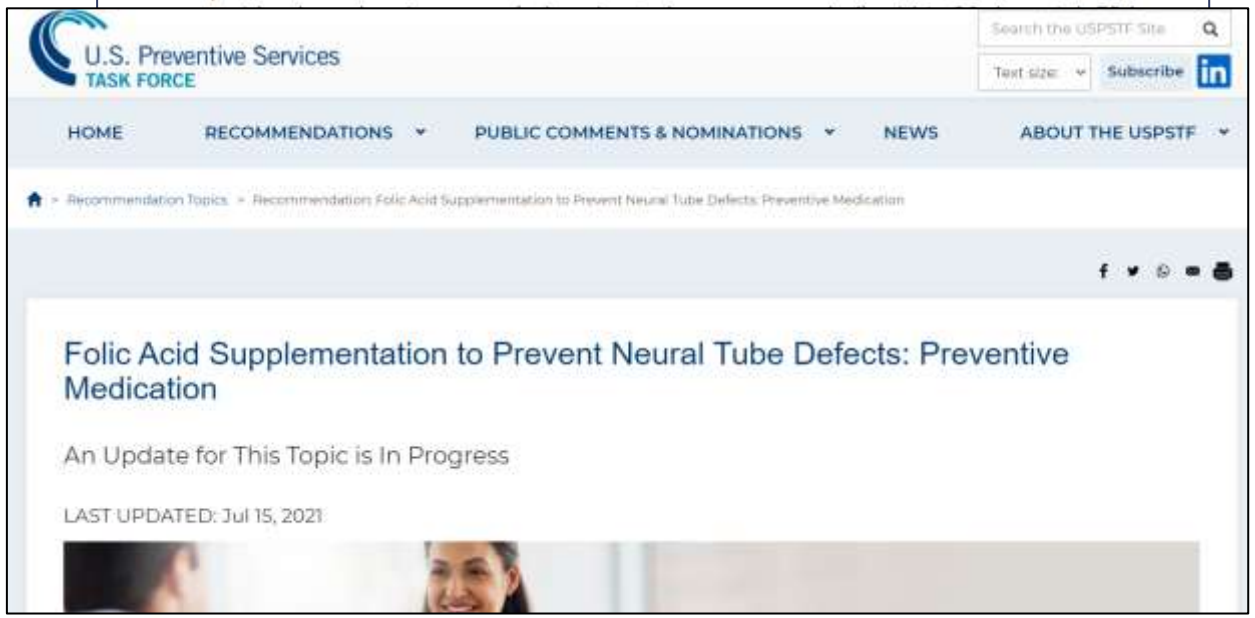
HEALTH

- First conjugate vaccine approved to treat an infectious disease[30]
- More than 90% of children in the U.S. receive the Hib vaccine[31]

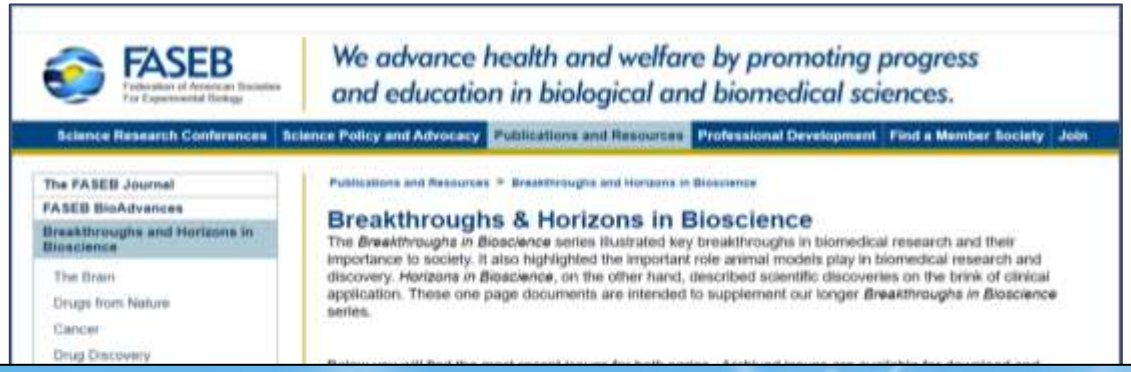
Incidence of Hib cases declined more than 99% following availability of the conjugate vaccine.[32]



NIH and its HHS Partners



NIH and Its Other Partners



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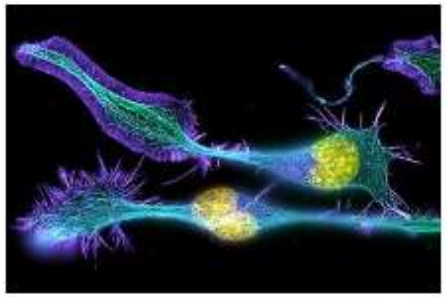
IMPACT OF NIH RESEARCH

Our Health

- Helping people live longer, healthier lives
- Making diseases less deadly
- Developing effective interventions to prevent and treat illness and disability

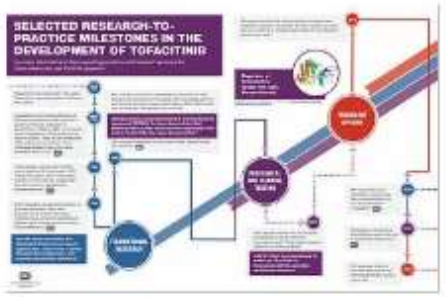
Our Society

- Supporting jobs in science and spurring economic growth
- Enabling a more productive economy
- Helping the U.S. compete and contribute internationally



Our Knowledge

- Driving the discovery and translation of innovative ideas
- Building the knowledge base to combat major health challenges
- Cultivating world-class scientists who create new knowledge



Our Stories

- Discovering a new class of rare diseases and showing that existing drugs can help patients
- Guiding the development of technologies that restore lost neurological function
- Helping to end the leading cause of childhood bacterial meningitis

Thank You & Questions