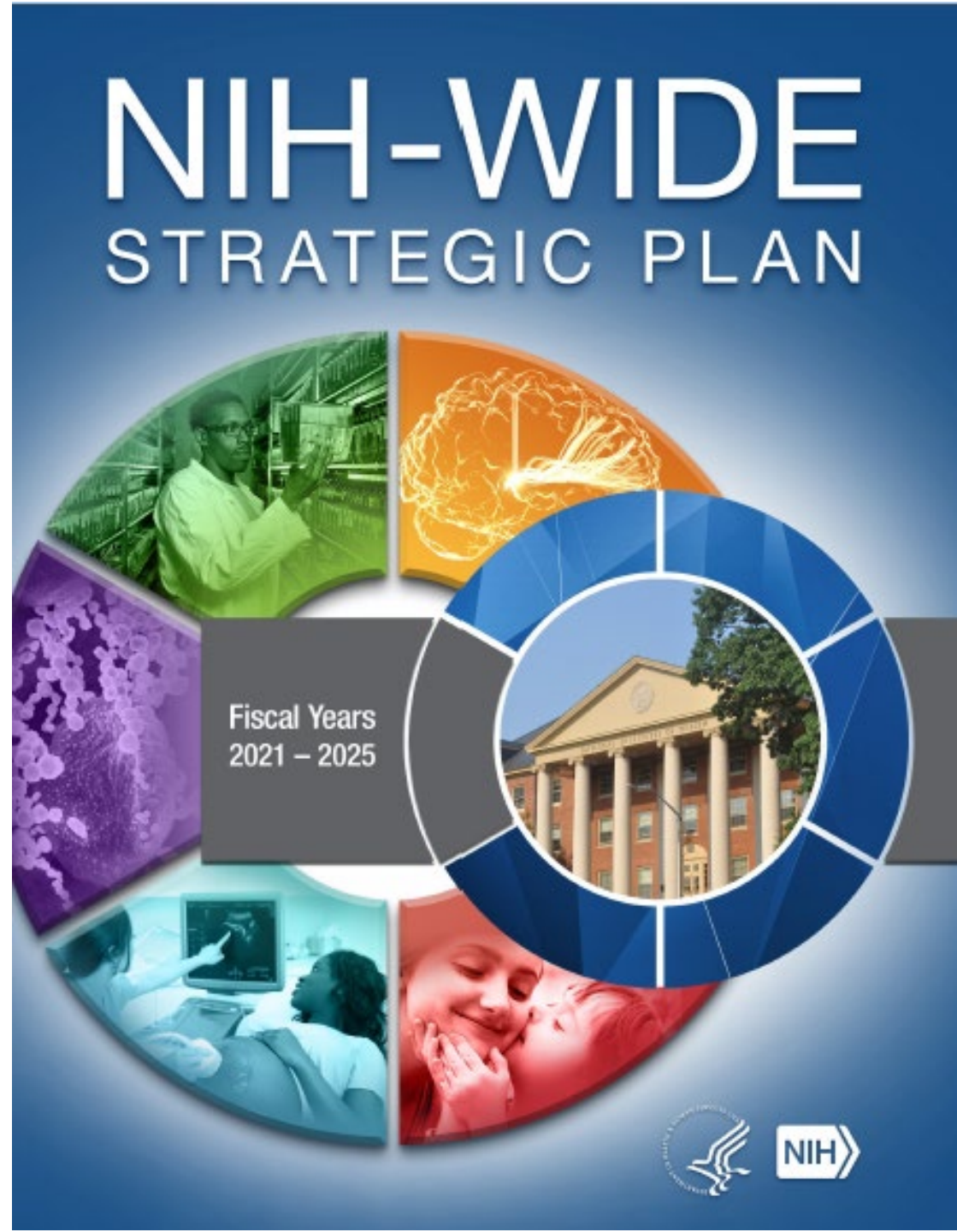


Developing the NIH-Wide Strategic Plan for FYs 2021-2025

JAMES M. ANDERSON, MD PHD
DIRECTOR, DPCPSI

COUNCIL OF COUNCILS MEETING, NOVEMBER 13, 2020

Time to Update the NIH-Wide Strategic Plan



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



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Development of the NIH-Wide Strategic Plan



Sep 2019 – Jan 2020

Phase 1: NIH Input &
Develop Strategic Plan
Framework



Jan 2020 – July 2020

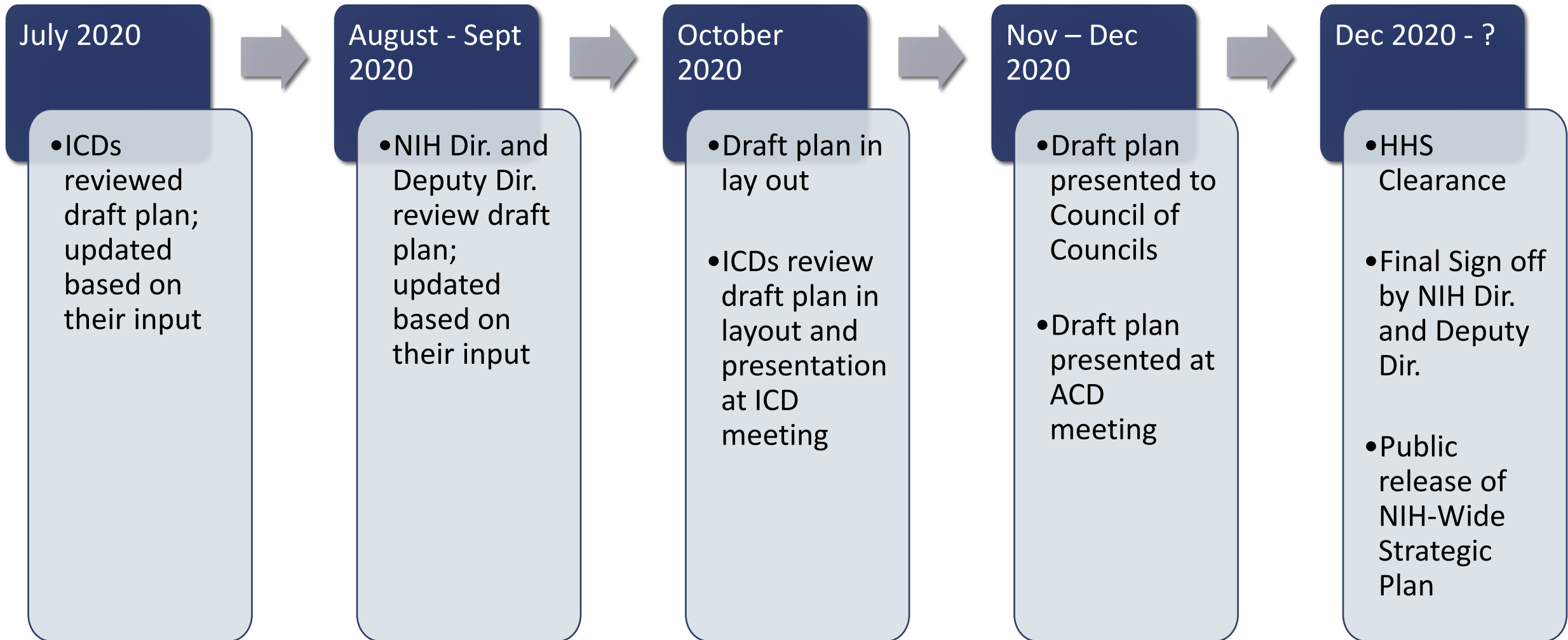
Phase 2: Public Input &
Draft Strategic Plan



July 2020 – ?

Phase 3: Approval Process

Phase 3: Strategic Plan Approval



Director's Message

Overview of NIH: Mission and Goals, Organization

NIH's Strategy

Objectives

Research Areas

- Foundational
- Disease Prevention/Health
- Treatments/Interventions/Cures

Research Capacity

- Workforce
- Infrastructure/Resources

Research Conduct

- Stewardship
- Partnerships
- Accountability/Confidence
- Management/Operations

Cross Cutting Themes

- Minority Health & Health Disparities
- Women's Health
- Public Health Challenges Across the Lifespan
- Collaborative Science
- Data Science

Bold Predictions

Appendices

Objective 1: Advancing Biomedical and Behavioral Sciences

Driving Foundational Science

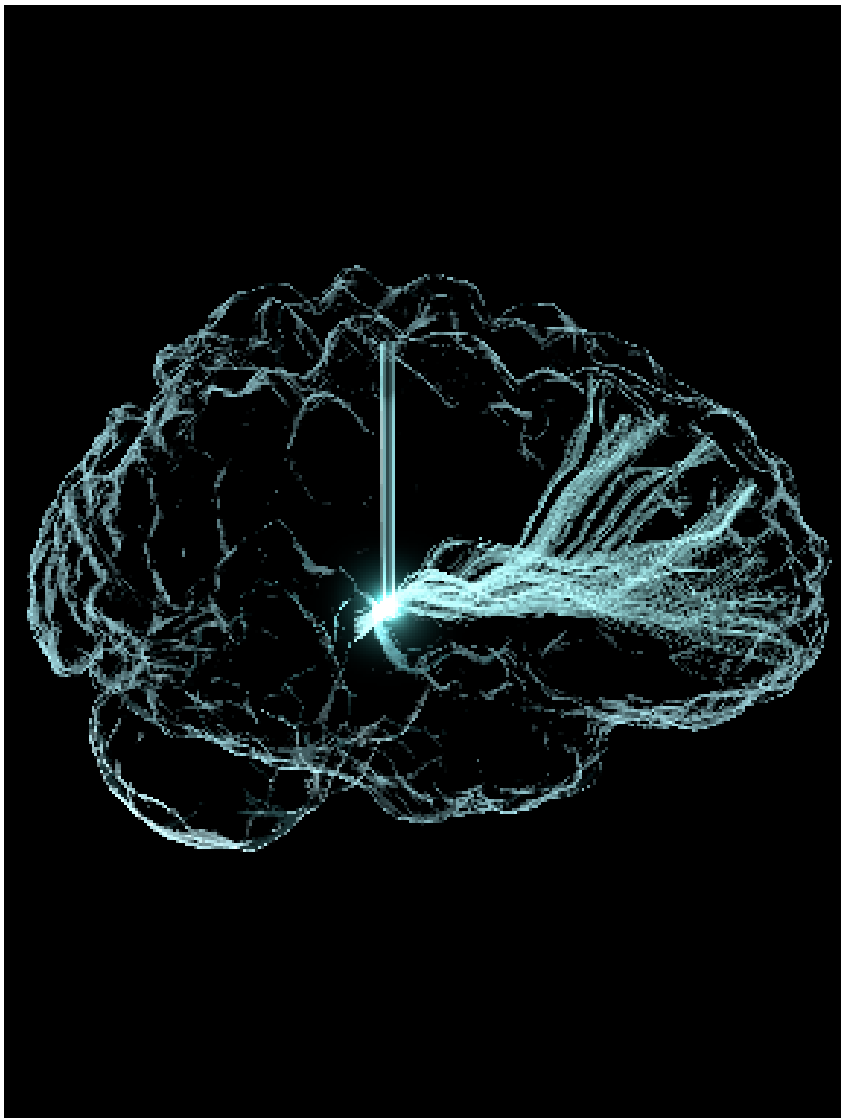
- Basic research
- Population science/
Epidemiology

Preventing Disease and Promoting Health

- Translational research
- Clinical research
- Implementation/
Dissemination research
- Population Science/
Epidemiology

Developing and Optimizing Treatments, Interventions, and Cures

- Translational research
- Clinical research
- Implementation/
Dissemination research
- Population Science/
Epidemiology



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.



Driving Foundational Science: The INCLUDE Project

INCLUDE (INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndrome) is an NIH-wide research initiative involving 18 ICs that aims to understand critical health and quality-of-life needs for individuals with Down syndrome.



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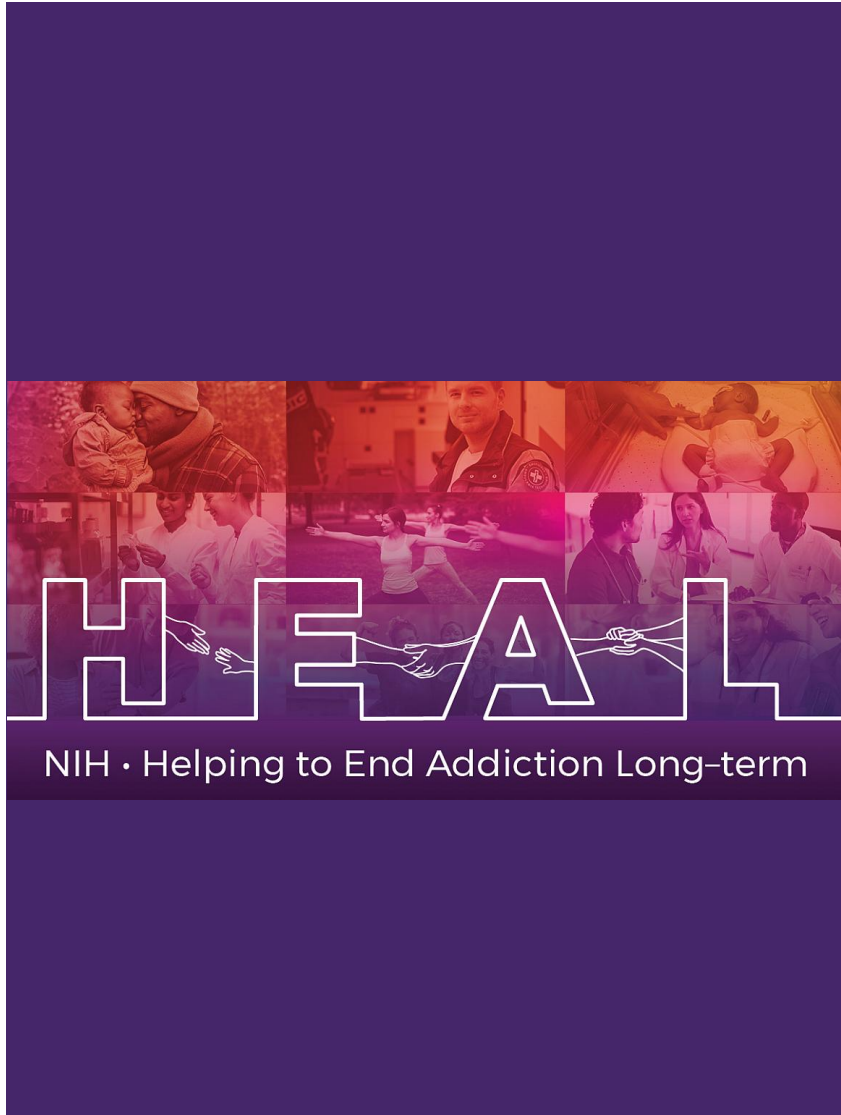
Preventing Disease and Promoting Health: Universal Flu Vaccine

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 InitiativeSM

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

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

Enhancing the Biomedical Research Workforce

- Strength of the workforce depends on its sustainability and diversity
- Overarching goals of training and career development programs

Supporting Research Resources and Infrastructure

- Must be expansive, durable, state-of-the-art and accessible
- Overarching goals of research resources and infrastructure support activities



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

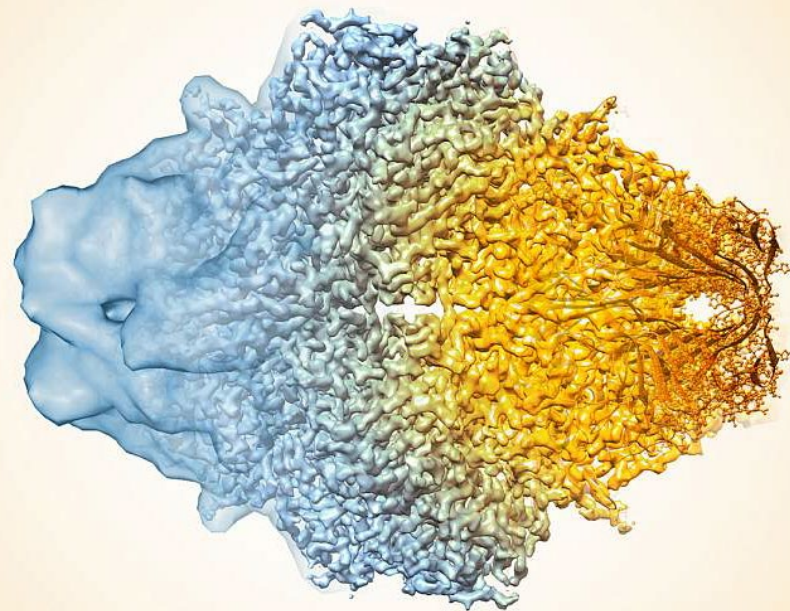
The NARI program supports American Indian and Alaska Native undergraduates from across the country in paid summer research internships at the University of Utah.

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.



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

Fostering a Culture of Good Scientific Stewardship

- Setting priorities
- Monitoring progress
- Others

Leveraging Partnerships

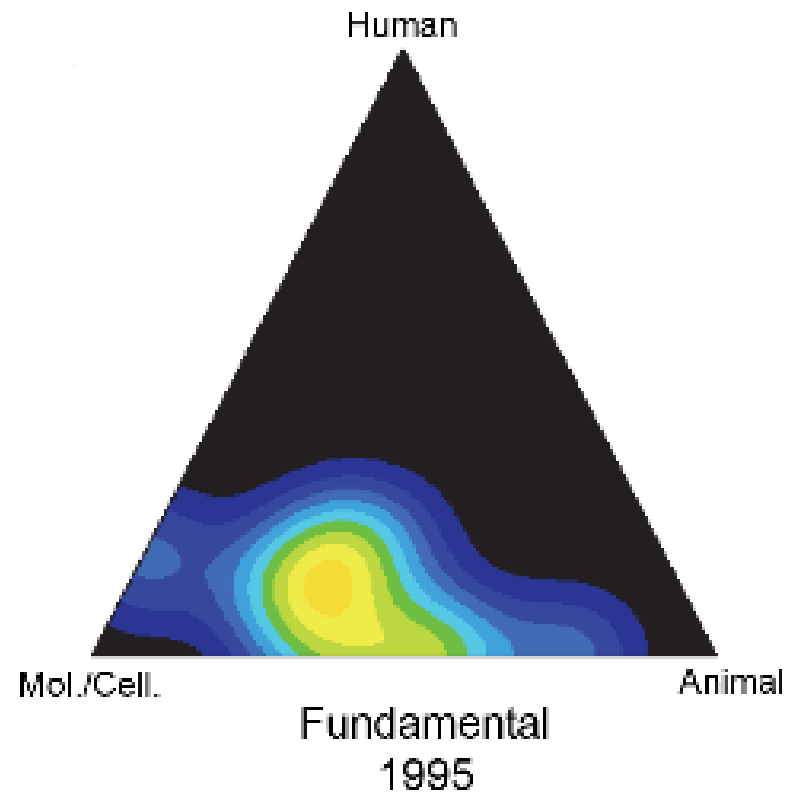
- Federal partners
- Public engagement
- Others

Ensuring Accountability and Confidence in Biomedical and Behavioral Sciences

- Ethical and equitable conduct of research
- Safe and harassment-free workplace
- Others

Optimizing Operations

- Increasing efficiency and effectiveness
- Improving NIH operations, business processes and coordination
- Others



Fostering a Culture of Good Scientific Stewardship: iCite and Translational Impact of Research

The iCite suite of tools is a public resource that enables users to examine validated metrics regarding the impact of NIH-funded research articles

Helps users to examine the NIH portfolio's productivity, balance, and priorities across the spectrum of research—from basic to clinical and across the diverse areas of biomedical and behavioral research



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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Leveraging Partnerships: Research for Pregnant and Lactating Women

The 21st Century Cures Act established the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) to advise the Secretary of HHS regarding gaps in knowledge and research on safe and effective therapies for pregnant women and lactating women.



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**HARASSMENT
DOESN'T
WORK HERE**

Ensuring Accountability and Confidence in Biomedical and Behavioral Sciences: Harassment

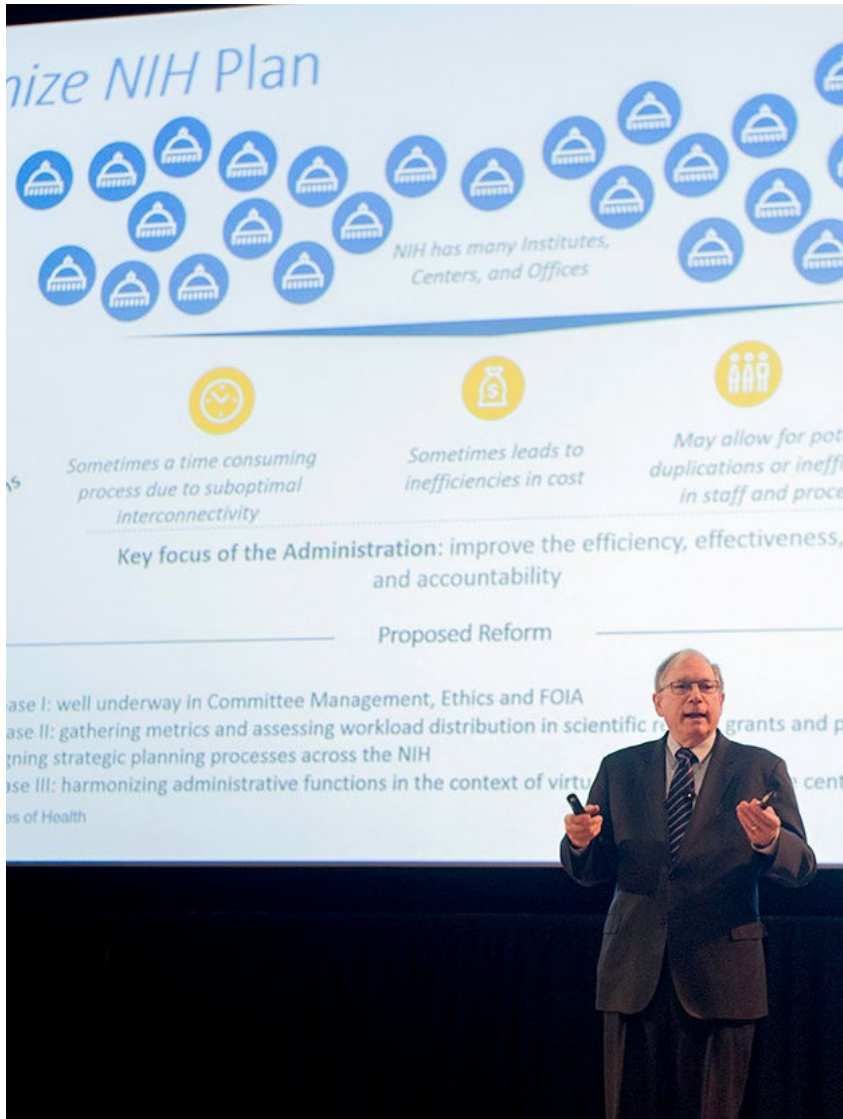
NIH has started a campaign to create a safe and civil workplace wherever NIH-funded research is conducted.

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.

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**

Background Slides

Strategic Plan Working Group

Working Group comprises members from all 27 ICs and 24 OD and DPCPSI offices

- **ICs:** CC (David Saeger), CIT (Valerie Virta), CSR (Hope Cummings), FIC (Rachel Sturke), NCATS (Meredith Temple-O'Connor, Nicole Garbarini), NCCIH (Mary Beth Kester), NCI (Michelle Bennett, Laura Brockway-Lunardi), NEI (Shefa Gordon, Nora Wong), NHGRI (Cristina Kapustij, Rebecca Hong), NHLBI (Dan Stimson), NIA (Kate Nagy), NIAAA (Bridget Williams Simmons), NIAID (Thomas Calder, Lara Miller), NIAMS (Reaya Reuss, Cindy Caughman), NIBIB (Chris Cooper), NICHD (Issel Anne Lim, Elizabeth Baden), NIDA (David Bochner, Julie Frost Bellgowan), NIDCD (Laura Cole), NIDCR (Denise Stredrick), NIDDK (Julie Wallace), NIEHS (Sheila Newton, Kimberly Thigpen Tart), NIGMS (Claire Schulkey, Eileen Oni), NIMH (Mindy Chai), NIMHD (Deb Duran, Nathan Stinson), NINDS (Paul Scott), NINR (John Grason), NLM (Leigh Samsel)
- **DPCPSI:** IMOD (Taylor Gilliland), OAR (Yvette Edghill Spano), OBSSR (Katie Morris), ODP (Wilma Peterman Cross), ODSS (Wynn Meyer), OEPR (Marina Volkov, Sarah Rhodes, Kelly Singel, Ira Kukic, Rosanna Ng), OPA (Rebecca Meseroll), ORIP (Patty Newman) ORWH (Samia Noursi, Ching-Yi Shieh), OSC (Stephanie Courchesne), SGMRO: (Ryan Mahon), THRO (Edmund Keane)
- **OD:** IMOD (Beth Walsh, Kamilah Rashid, Erica Landis), All of Us (Ned Culhane), COSWD (Charlene Le Fauve), ECHO (Leslie Thompson), HEAL (Erin Spaniol), OCPL (Stephanie Clipper), OER (David Kosub), OIR (Chuck Dearolf), OLPA (Laura Berkson), OM/OMA (Meredith Stein), OM/ORF (Clarence Dukes), OSP (Tyrone Spady, Jessica Creery)

Strategic Plan Content

Process used to gather content from across NIH for the Strategic Plan

1. Dr. Anderson sent Data Call to ICDs for **accomplishments and new initiatives** aligned with each Objective.
 - Cc'd WG members and/or P&E officers.
2. Working Group held discussions to identify **additional** content.
3. Working Group identified **prioritized content** to put forward to leadership, based on balance across subject matter, ICOs, accomplishments and new initiatives, etc.
 - i. WG members voted on top submissions from other ICOs.
 - ii. WG subgroup reviewed submissions and identified priorities based on voting and balance.
 - iii. Full WG agreed on prioritized content prior to sending forward to leadership.
4. NIH Leadership provided **feedback** on content/priorities.

ICD Review of the draft Strategic Plan

- Dr. Anderson requested ICD feedback on draft Plan in July
- 21 ICDs and 20 OD office Directors responded
 - 9 ICDs and 6 OD office Directors reviewed the plan and provided comments
 - 10 ICDs and 7 OD office Directors reviewed the plan and confirmed no comments
 - 1 ICD and 7 OD office Directors chose to not review the plan because their WG rep had consulted them frequently throughout the process
 - 1 ICD (Dr. Tabak for NIDCR) declined to review the plan at this time and waited to review with NIH leadership

Request for Information (RFI) Process

- RFI conducted to gather public input on the NIH-Wide Strategic Plan Framework:
 - Public responses collected via webform
 - Strategic Planning mailbox set up to answer questions
- To maximize public response, the RFI was:
 1. Advertised widely:
 - NIH Guide
 - Federal Register
 - NIH website landing page
 - NIH Twitter
 2. Open for 7 weeks (2/12 – 4/1)
 - Included a 1-week extension requested by members of the public due to COVID-19
- Coordinated with OER (publishing) and OCPL (rollout)

Request for Information (RFI) Responses

- Received responses from **160 individuals/organizations**.
 - Respondents came from a **variety of organizations**, including 56 from academic institutions, 29 from professional societies, 27 from advocacy groups, 16 from the public, 9 from the private sector, 7 from government agencies, 6 from health professionals, 3 from scientific research organizations (non-academic), and 7 from other types of organizations not listed.
 - Respondents represented a **variety of roles within their organizations**, including mid-level leadership (60 respondents), senior leadership (46 respondents), members of the public (32 respondents), administrative staff (13 respondents), clinical and/or research staff (7 respondents), graduate students (1 respondent), and other roles (1 respondent).
- **RFI report** to be posted online after Strategic Plan is released.

Webinar Process

Two webinars held to present the strategic planning process to the public and answer questions.

- Presented by Dr. Anderson
- **Attendees** from academia, general public, professional societies/advocacy groups, and industry.
 - March 9, 2020: 134 attendees.
 - March 16, 2020: 93 attendees.
- Advertised via **NIH Twitter** and **Strategic Planning** website.
 - Liaised with OCPL for rollout plan
- Slides and transcripts on will posted on **Strategic Planning** website at later date.

Process for Drafting the Strategic Plan

To draft and incorporate edits to the Strategic Plan.

- WG members divided into 10 writing groups based on Framework.
 - Overview, Themes, Foundational, Prevention, Treatments/Cures, Workforce/Infrastructure, Stewardship Pipeline, Partnerships, Accountability/Confidence, and Management/Operations.
- Convened writing groups at various stages.
 - To develop initial draft.
 - To review and incorporate public input.
 - To incorporate ICD feedback.



Objective 1: **Developing Treatments, Interventions, and Cures:** Cure Sickle Cell Initiative

NIH launched the Cure Sickle Cell Initiative to move promising gene-based curative therapies safely into clinical trials within 5-10 years.

Recently funded projects include a new platform to manufacture therapeutic products in large quantities, and a national data resource that will help provide a more comprehensive picture of sickle cell disease.



Objective 1: **Driving Foundational Science:** Adolescent Brain Cognitive Development (ABCD) Study

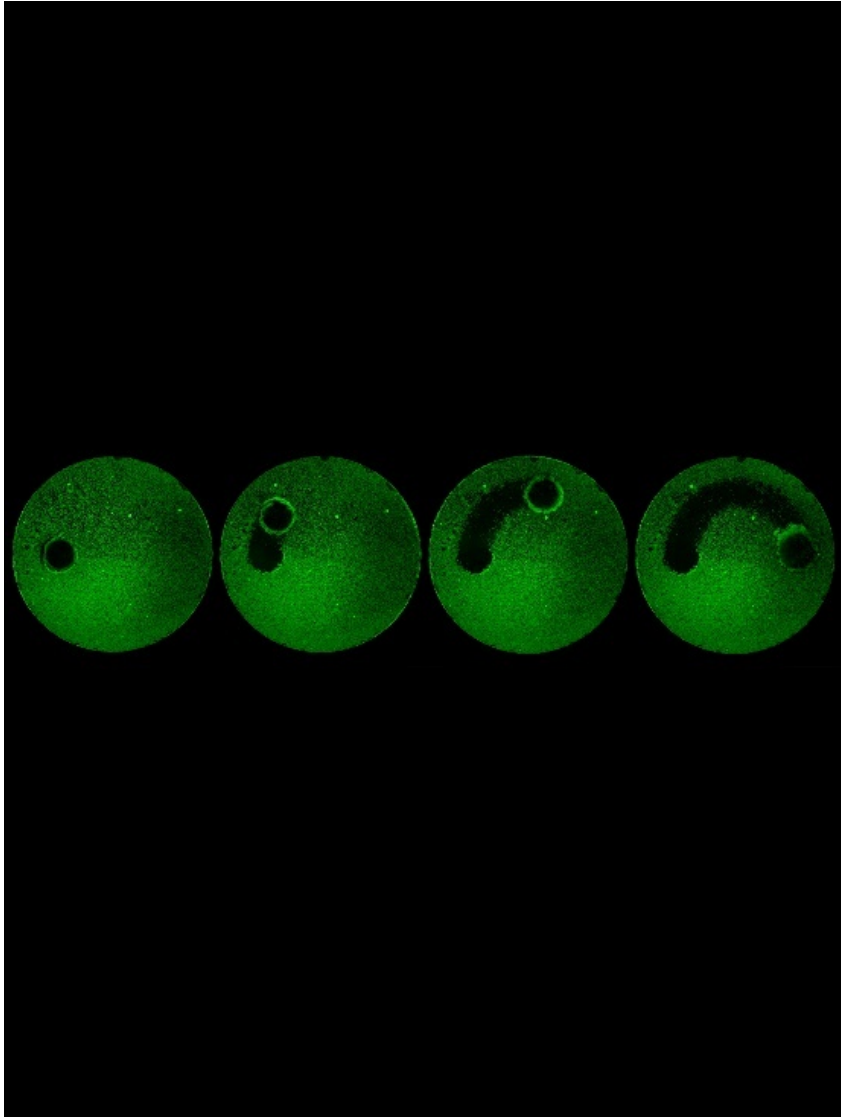
Largest long-term study of brain development and child health in the U.S.

Has recruited over 11,000 children ages 9-10, whom it will follow into adulthood.



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Objective 1: Preventing Disease and Promoting Health: Nanorobots for Dental Health

NIH supported a collaboration among biomedical researchers and engineers to build microscopic nanorobots to target, destroy, and remove dental plaque.



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Objective 1: Preventing Disease and Promoting Health: Systolic Blood Pressure Intervention Trial (SPRINT)

SPRINT found that maintaining systolic blood pressure at less than 120 mm Hg reduced the combined risk of heart attack, heart failure, and stroke by 25 percent and reduced the risk of death by 27 percent compared to the standard blood pressure target at the time (140 mm Hg).



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Objective 1: Developing Treatments, Interventions, and Cures: Artificial Pancreas to Better Manage Diabetes

A milestone was achieved in 2016 when FDA approved the first commercial “hybrid artificial pancreas” device.

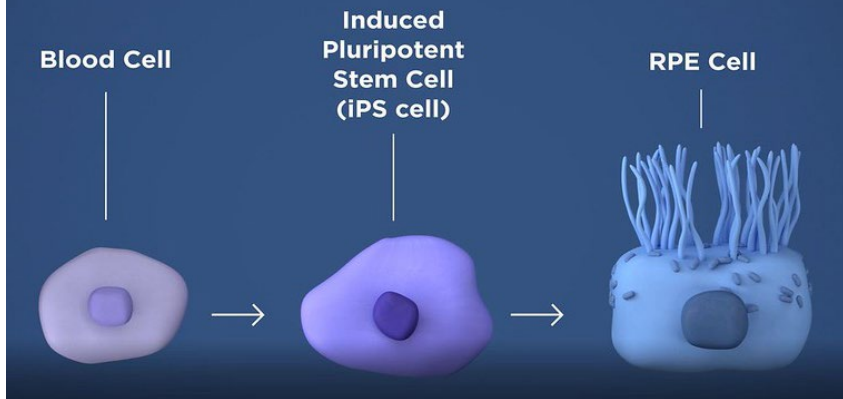
In 2019, the FDA approved the first interoperable system that could give patients the ability to choose the individual components that work best for them.



Objective 1: Developing Treatments, Interventions, and Cures: iPSCs for Age-Related Macular Degeneration

Researchers derived induced pluripotent stem cells (iPSCs) from participants with advanced Age-related Macular Degeneration and converted them into healthy retinal tissue to replace damaged tissue and prevent blindness in animal models.

NIH received FDA approval to begin the first-ever clinical trial using replacement tissue derived from iPSCs in humans.

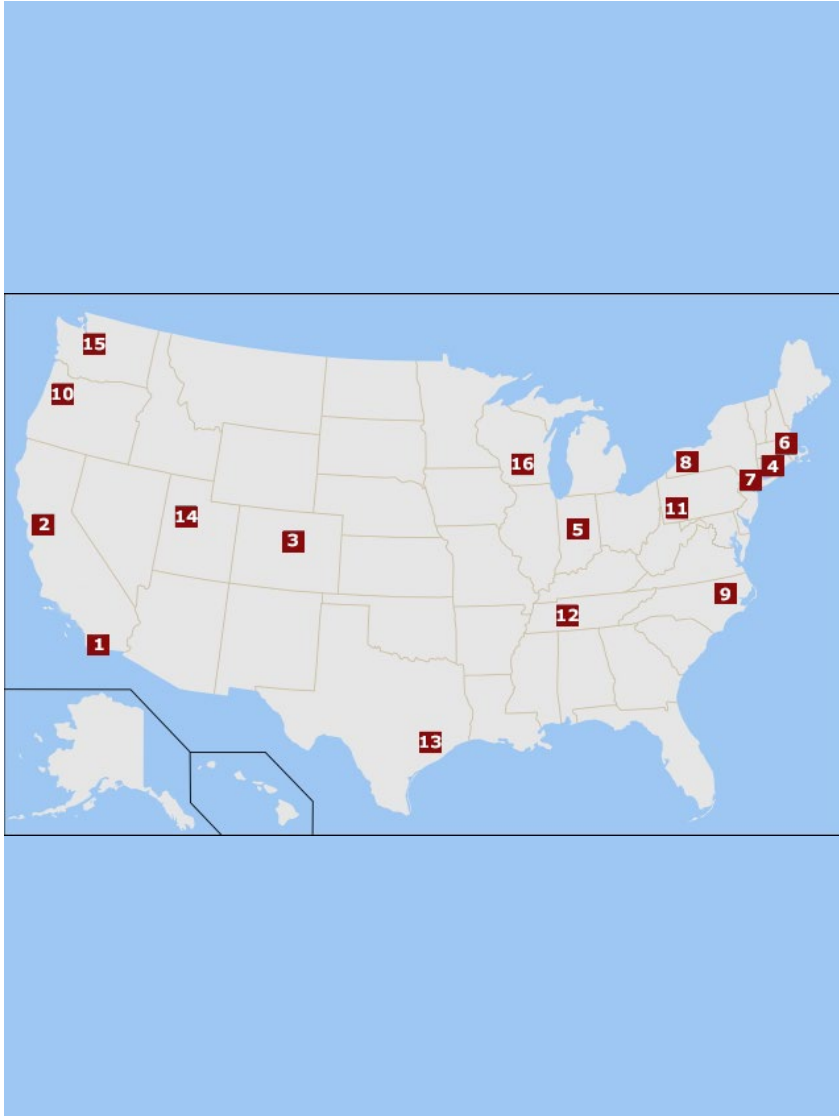


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Objective 2: Enhancing the Biomedical Research Workforce: Informatics and Data Science Research Training Programs

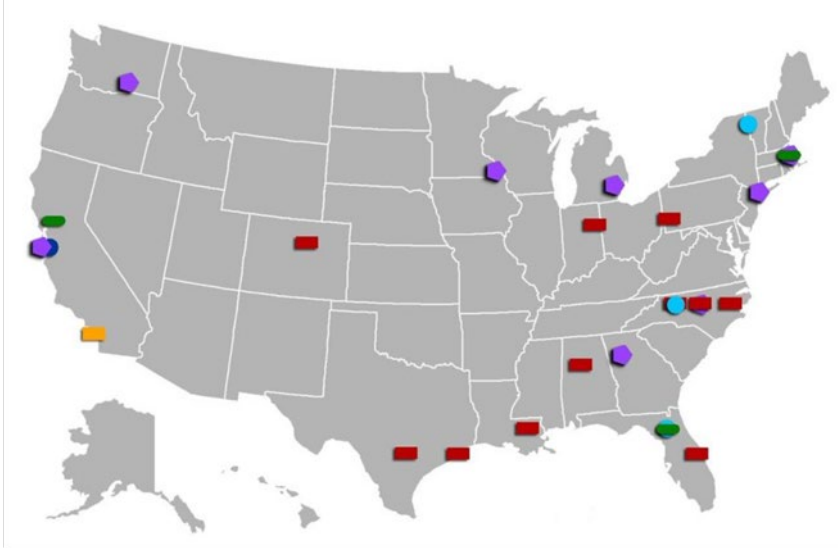
NIH supports 16 university-based training programs in biomedical informatics and data science, supporting more than 200 Ph.D.- and post-doctoral-level research trainees.



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Objective 2: **Supporting Research Resources and Infrastructure:** Molecular Transducers of Physical Activity Consortium



The goal is to build a map of the molecular responses to short- and long-term exercise that any investigator can use to develop and test hypotheses regarding how exercise improves health and ameliorates disease.

Released its first dataset through the MoTrPAC Data Hub in October 2019.



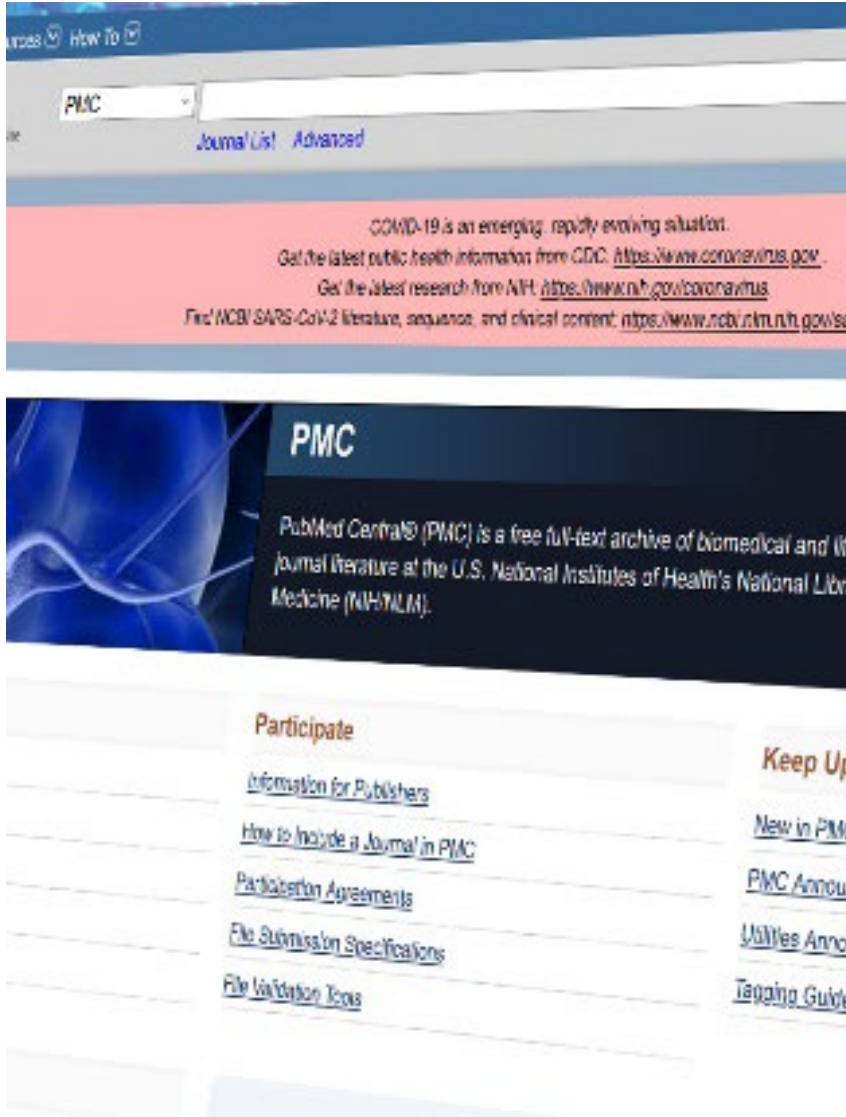
Objective 3: Fostering a Culture of Good Scientific Stewardship: Early Career Reviewer Program

Will help NIH refresh and diversify its pool of reviewers, while also helping investigators improve their grant writing skills, develop research evaluation capacity, and strengthen critique-writing skills



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Objective 3: 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.



Objective 3: **Leveraging Partnerships:** Interagency Pain Research Coordinating Committee

Coordinates federal activities to enhance pain research efforts and promote collaboration across the government, with the ultimate goals of advancing the fundamental understanding of pain and improving pain-related treatment strategies.



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Objective 3: Ensuring Accountability and Confidence in Biomedical and Behavioral Sciences: Inclusion

NIH requires researchers who propose research involving human subjects to include plans for how participants from underrepresented and underserved groups will be enrolled, unless there is a scientific or ethical justification for their exclusion.



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FY 2016-2020 NIH-Wide Strategic Plan Outline

➤ Overview

➤ NIH's Strategy

- **Objective 1:** Advance Opportunities in Biomedical Research
 - *Fundamental Science*
 - *Treatments and Cures*
 - *Health Promotion and Disease Prevention*
- **Objective 2:** Foster Innovation by Setting Priorities
- **Objective 3:** Enhance Scientific Stewardship
- **Objective 4:** Excel as a Federal Science Agency by Managing for Results

➤ A Few Bold Predictions for America's Future



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