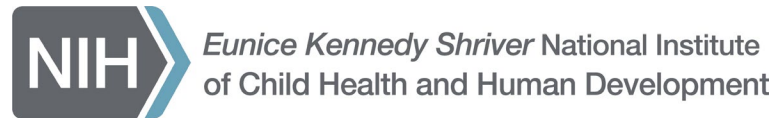


NICHD Director's Report ***NACHHD Meeting***

Diana W. Bianchi, M.D.

June 3, 2024



Talk Outline

- FY25 President's Budget and Congressional Interactions
- NICHD's Research Portfolio and Strategic Planning
- Women's Health
 - Women's Health Research Initiative, Endometriosis, IMPROVE Initiative
- Pediatric Research
 - Digital Media, *All of Us*, Medical Devices, N-PeRC
- Updates on Key NIH Programs and Policies
- Kudos!
- NIH and NICHD Staff Updates



FY25 President's Budget Congressional Interactions

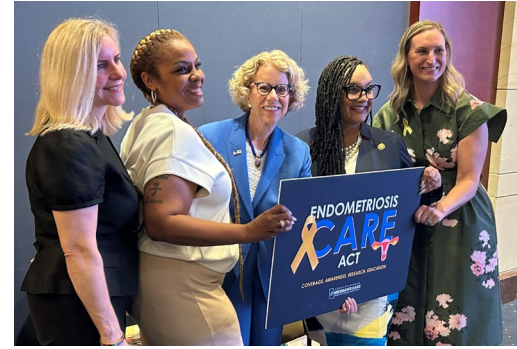
FY25 President's Budget

- \$50.1B for NIH
- \$1.77B for NICHD
- Women's Health Research
 - New nationwide network of centers of excellence and innovation in women's health
 - Proposed doubling funding for the Office of Research on Women's Health at NIH
- Senate Appropriations LHHS Subcommittee hearing May 23 (Congress appropriates)



Congressional Interactions

- Rep. Lauren Underwood (IL) - menopause and maternal health research
- Rep. Julia Letlow (LA) - maternal health and women's health research
- Women's Congressional Policy Institute
 - Update on IMPROVE initiative and maternal mortality
- ACT for NIH 10th anniversary event
- Re. Nikema Williams (GA) - Endometriosis CARES Act



WOMEN'S
CONGRESSIONAL
POLICY INSTITUTE

ACT for **NIH**
ADVANCING CURES TODAY



Congressional Interactions – Staff-to-Staff Briefings

- Rep. Juan Ciscomani (AZ) - gynecologic health and disease research, NICHD's major clinical trial networks, and use of pharmaceuticals during pregnancy
- Rep. Katherine Clark (MA) - women's health research
- Rep. Anna Eshoo (CA) - challenges in pediatric drug development
- Sen. Tim Scott (SC) - ACT NOW (neonatal opioid withdrawal), maternal health and the IMPROVE initiative, and RADx Tech for Maternal Health Challenge



NICHD's Research Portfolio

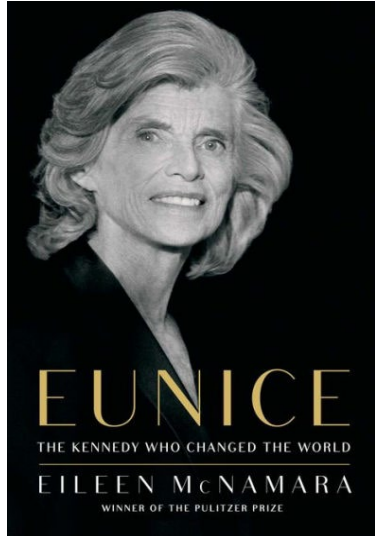
Eunice Kennedy Shriver

National Institute of Child Health and
Human Development

~30%

Reproductive
Health

~15% Intellectual and Developmental
Disabilities and Rehabilitation



~55% Pediatrics



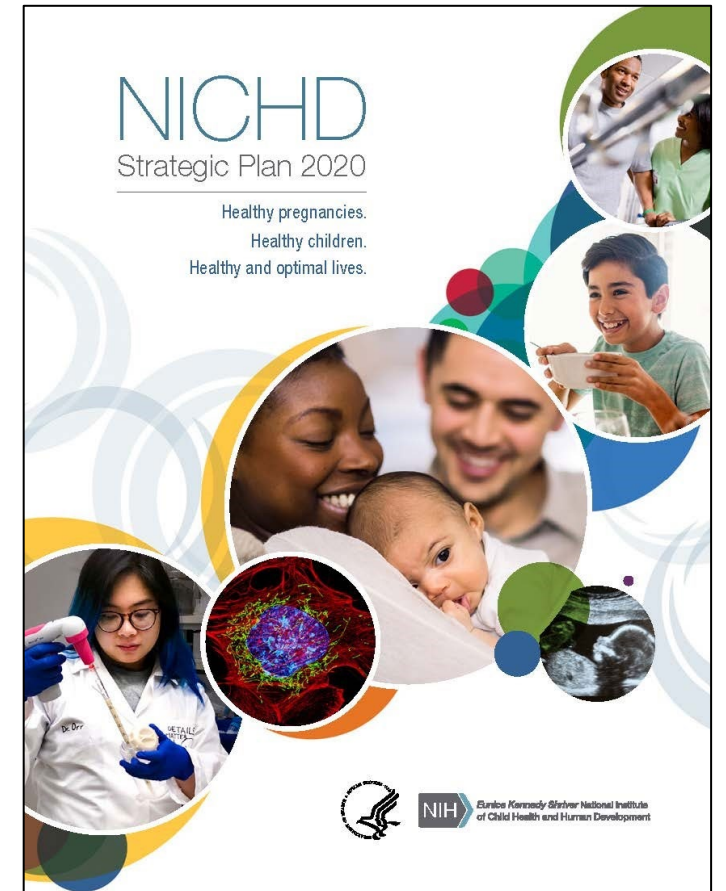
NICHD Strategic Plan 2020

Research Themes

- Understanding the Molecular, Cellular, and Structural Basis of Development
- Promoting Gynecologic, Andrologic, and Reproductive Health
- Setting the Foundation for Healthy Pregnancies and Lifelong Wellness
- Improving Child and Adolescent Health and the Transition to Adulthood
- Advancing Safe and Effective Therapeutics and Devices for Pregnant and Lactating Women, Children, and People with Disabilities

NICHD 2025 Strategic Plan

- NICHD Strategic Plan 2020 spans 5 years
 - Research, Stewardship, Management and Accountability
 - NICHD has been documenting and tracking activities and achievements towards current objectives
- Refreshing the Strategic Plan over the next year
- Request for Information to solicit external feedback from the public anticipated in August 2024
- Strategic Plan Update anticipated to be released early spring 2025



Women's Health “Below the Belt”



Gynecologic Health and Disease

Contraception Research

Fertility and Infertility

Pregnancy and Perinatology

Maternal and Pediatric Infectious Disease

Obstetric and Pediatric Pharmacology and Therapeutics

Population Dynamics

White House Women's Health Research Initiative (WHRI)

- [Executive Order on Advancing Women's Health Research and Innovation](#)
 - Cross-government initiative to promote collaborative, interdisciplinary research
 - Assess unmet needs in women's health research
 - Develop a research agenda and common data elements related to menopause
- NIH actions related to the Executive Order
 - Notice of Special Interest on Women's Health Research:
<https://grants.nih.gov/grants/guide/notice-files/not-od-24-079.html>
 - “Front door” collection of all NIH grant opportunities related to women's health research
- Funds for the WHRI have not yet been appropriated



Demand for Innovation in the Diagnosis of Endometriosis

- Despite affecting ~1 in 10 women, endometriosis is difficult to diagnose in part due to wide-ranging symptomatology that overlaps with other conditions
- Currently no reliable blood test or other non-invasive diagnostics
 - Gold standard diagnosis depends on laparoscopic visualization
 - Instead, clinicians rely on medical history, physical exam, and imaging
 - These tests cannot detect many forms of endometriosis, especially in smaller lesions
- **Innovation gap - develop reliable, non-invasive tests that enable early and accurate endometriosis diagnosis, which facilitates treatment**



RADx® Tech ACT ENDO Challenge

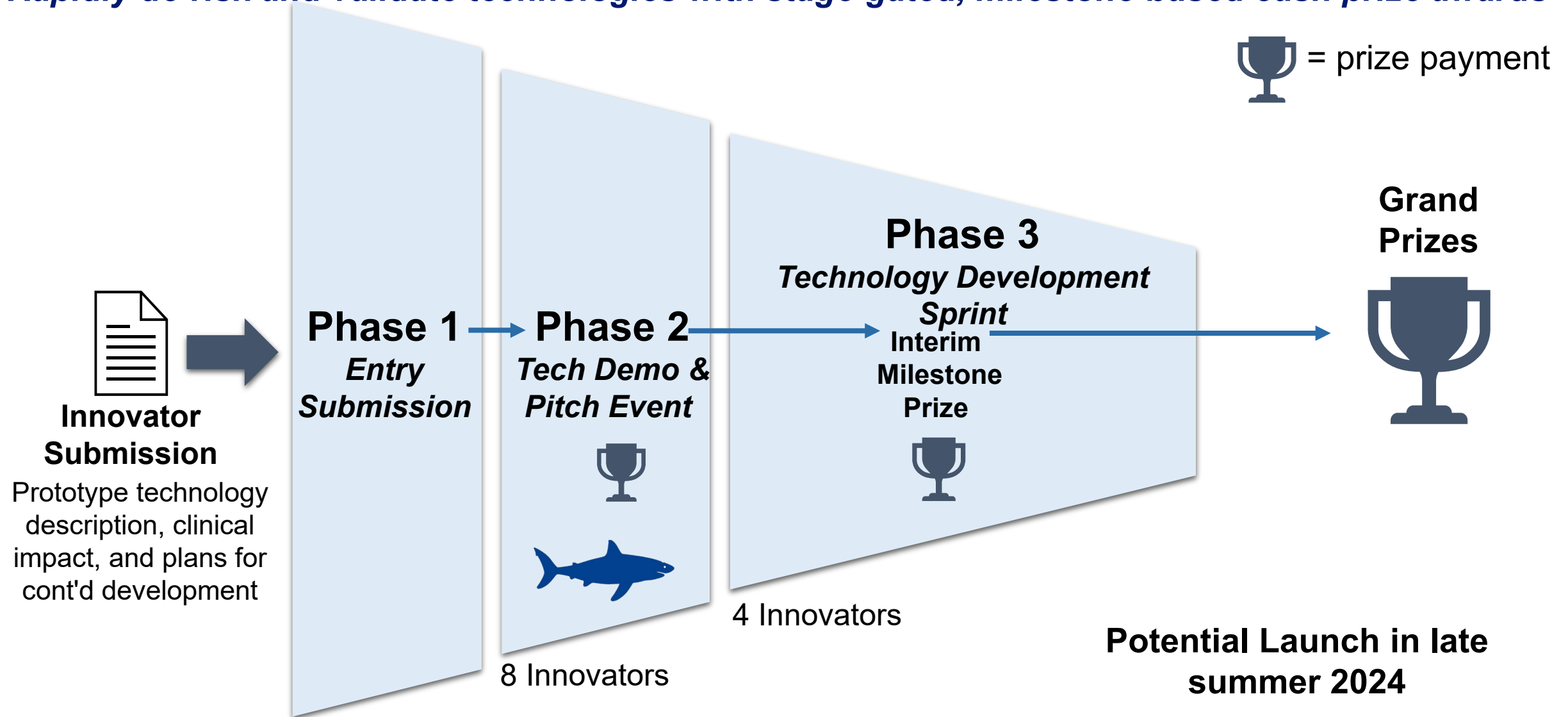
Advancing Cures and Therapies and ending ENDOMETRIOSIS diagnostic delays (ACT ENDO)

- **Problem:** Despite the prevalence and severe impact of this disorder on quality of life, diagnosis can be delayed up to 10 years
- **Solution:** NICHD, in partnership with NIBIB, will leverage the Rapid Acceleration of Diagnostics Technology (RADx® Tech) "innovation funnel" program
 - Accelerate the time to diagnosis, eliminate invasiveness of current techniques, and/or improve accessibility, safety, convenience, and cost of diagnosis
- **Approaches** (not exclusive):
 - Utilize new or existing biomarkers from serum, saliva, or menstrual effluent
 - Distinguish between benign and malignant endometriosis
 - Utilize epigenetic or genomic data with machine learning to diagnose early disease states



RADx® Tech ACT ENDO

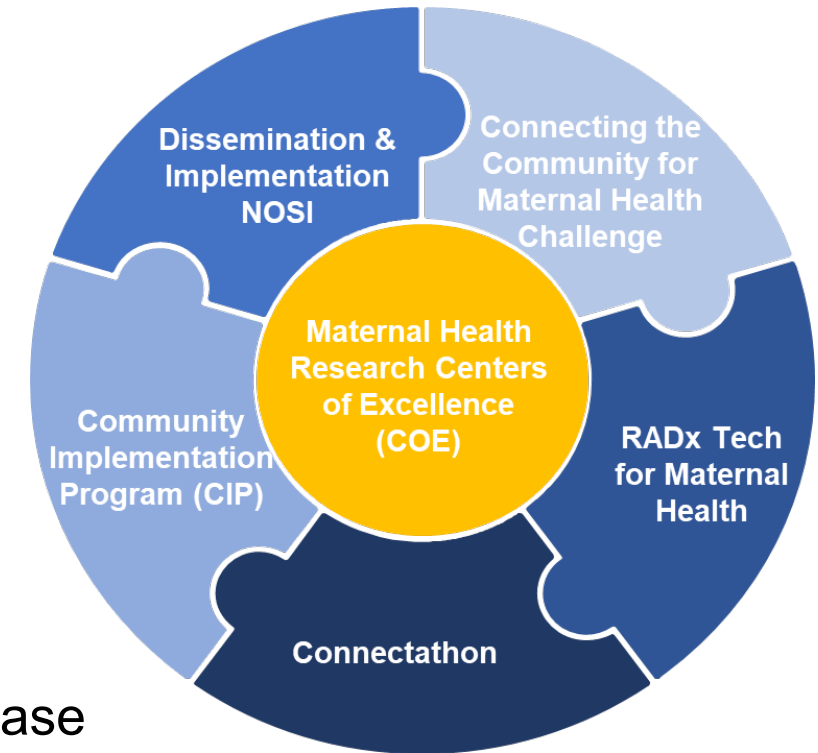
Rapidly de-risk and validate technologies with stage-gated, milestone-based cash prize awards



Updates on Major IMPROVE Initiatives

Implementing a Maternal health and Pregnancy Outcomes Vision for Everyone

- 10 Maternal Health Research Centers of Excellence
 - Data Hub and Implementation Science Hub
- **RADx Tech for Maternal Health challenge** for postpartum diagnostics and monitoring
 - **Final winners anticipated in October 2024**
- **Connecting the Community for Maternal Health Challenge** to build research infrastructure in communities
 - **Final winners announced in September 2024**
- Community Implementation Program supporting research to increase intervention uptake in community settings
- Developing electronic health record standards for pregnancy to enable real-world research



Pediatric Research



Developmental Biology and Congenital Anomalies

Child Development and Behavior

Intellectual and Developmental Disabilities

Pediatric Growth and Nutrition

Pediatric Trauma and Critical Illness

Maternal and Pediatric Infectious Disease

Obstetric and Pediatric Pharmacology and Therapeutics

Population Dynamics

Effects of Technology and Digital Media Use on Children

- NICHD-NIMH Workshop: Impact of Technology and Digital Media on Child and Adolescent Development and Mental Health (April 4-5, 2024)
 - Discussed current state and future directions for research
 - Both positive and negative effects of technology and digital media on developmental and mental effects
 - Meeting recording available:
<https://web.cvent.com/event/3bde75f7-33d7-41c0-a3e5-6b3c2ad9041b/summary>



All of Us #1 Program Priority in 2023/2024: Enabling Pediatric Participation



Pediatric Team

- Established the Pediatric Branch of Division of Cohort Development
- Coordinated across *All of Us*, NIH, and partner sites & organizations



Pediatric Protocol

- Wrote or amended protocol and appendices
- **IRB approved for participants birth to 5 years of age**



Participant and Staff Platforms

- **Adapted all tech** to support pediatric participation
- Data capture for surveys, physical measures, biospecimens



Site Selection and Onboarding

- Identified and onboarded **5 initial sites** for assessment of systems



Training

- Deployed program and site-specific training



End to End Readiness Assessment

- **Successful test of all systems and processes by enrolling a small number of pediatric participants**

***All of Us* is now poised to scale-up pediatric enrollment efforts.**



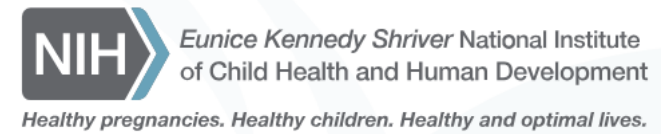
NIH Pediatric Research Consortium (NPeRC)

- Established in 2018 to increase collaboration and coordination of pediatric research across NIH
- Focus areas thus far include:
 - Transition from adolescent to adult healthcare
 - Workshop and NOSI
 - COVID-19
 - Funding for pediatric research
 - Pediatric pain research
 - Collaboration with HEAL initiative
- Pediatric clinical trials
- **Pediatric research workforce**
- **Pediatric medical devices**
 - Public-private partnership



Pediatric Medical Devices PPP

- Public partners include NICHD, NIBIB, BARDA, FDA
- Private sector partners include FNIH, American Academy of Pediatrics, academic institutions, children's hospitals, pharmaceutical companies of varying sizes, and non-profit organizations
- Aims:
 - Consolidate a national ecosystem to accelerate advancements in medical devices designed, evaluated, and approved for pediatric populations.
 - De-risk and streamline processes enabling translation of medical advances from bench to bedside for medical devices for children.
 - Ultimately address the lack of access to medical device options designed and approved for the pediatric population.





Updates on Key NIH Programs and Policies

NIH Program to Support Clinical Research in Primary Care Settings

Goals:

- Establish a **primary care-focused** clinical research network that is disease-agnostic, facilitating clinical research **in mission areas across all ICs**
- **Integrate innovative research** with routine clinical care in real-world settings
- Create a foundation for sustained **engagement with communities underrepresented in clinical research**

Anticipated Budget: OD funds \$5M in FY24, \$25M in FY25; anticipate ramp up of ~\$50-100M/year after assessing feasibility and budget requirements

Timeline: Gather Feedback in Spring 2024 → Quick Launch in 2024 (ROA applications due June 14) → Expand in 2025 and Beyond

<https://commonfund.nih.gov/clinical-research-primary-care/Primary-care-research-network-Research-Opportunity-Announcement-FY24>



Increase in FY 2024 Pre- and Post-doctoral Stipends

- Stipends will be raised by ~4% for predoctoral trainees and by ~8% for postdoctoral scholars in FY24 compared to last year
 - Most substantial year over year increase since FY 2017
 - NIH selected the current plan to allow for an immediate pay increase without drastic cuts to the number of available NRSA awards, though a small reduction in the number of positions is expected
 - As appropriations and budget realities allow, NIH's goal is to reach the Advisory Committee to the NIH Director recommended stipend levels (around \$70,000 per year for postdoctoral scholars) in the coming years
- Additionally, the childcare subsidy will be increased by an additional \$500 (from \$2500 to \$3000) in FY24



What Will Change Under the Simplified Review Framework for Research Project Grants?

- Existing five review criteria reorganized into three factors
- Investigator/Environment will be evaluated as sufficient or gaps identified (considered in overall impact score, but no individual score)
- Some Additional Review Criteria (inclusions, study timeline) related to human subjects to be evaluated within Factor 2, for more rigorous review
- Most Additional Review Considerations shifted from reviewers to NIH staff
- Applies to applications submitted for January 25, 2025 due dates and beyond (summer 2025 peer review and October 2025 Advisory Council)

Facilitate the overarching goal of peer review: identification of the strongest, potentially highest-impact research





Kudos!

NIH Distinguished Investigator Dr. Gisela Storz Elected AAAS Fellow

- Leads NICHD's intramural Section on Environmental Gene Regulation
- Honored for “*distinguished contributions to the field of microbiology, particularly on the role of non-coding RNAs in gene regulation and on mechanisms of the oxidative stress response in bacteria and yeast.*”





NIH and NICHD Staff Updates

New NIH Institute and Center Directors



Sean Mooney, PhD
Center for Information Technology



Kathryn Neuzil, MD
Fogarty International Center

Director of the National Library of Medicine
position is now posted!

<https://hr.nih.gov/jobs/search/executive/job-87536>



We're Hiring!

- Extramural Branch Chiefs, Program Officers, Extramural Policy Officers
- Intramural Labs (postdocs, fellows, trainees)

<https://www.nichd.nih.gov/about/jobs>



Thank You! Questions?



**Check out our new
1-page fact sheets
on women's health
topics!**

