

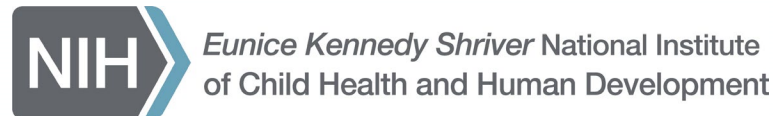
# **NICHD Strategic Plan Refresh:** Research Objectives and RFI Updates

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Office of Science Policy, Reporting and Analysis (OSPRA)

NICHD Advisory Council

September 4, 2024



# Agenda

- Overview of Strategic Plan Refresh Progress To-Date
- Overview of the Refreshed Research Objectives
- RFI Comment Period – NICHD Strategic Plan 2025



# NICHD 2020 Strategic Plan: Overall Structure

## Scientific Research



### Goals/Themes

- Development
- Gynecology and Andrology
- Pregnancy and Perinatology
- Child Health
- Therapeutics

### Cross-cutting Themes

- Global health
- Health disparities
- Infectious diseases
- Nutrition
- Prevention

### Aspirational Goals

## Scientific Stewardship



### Goals

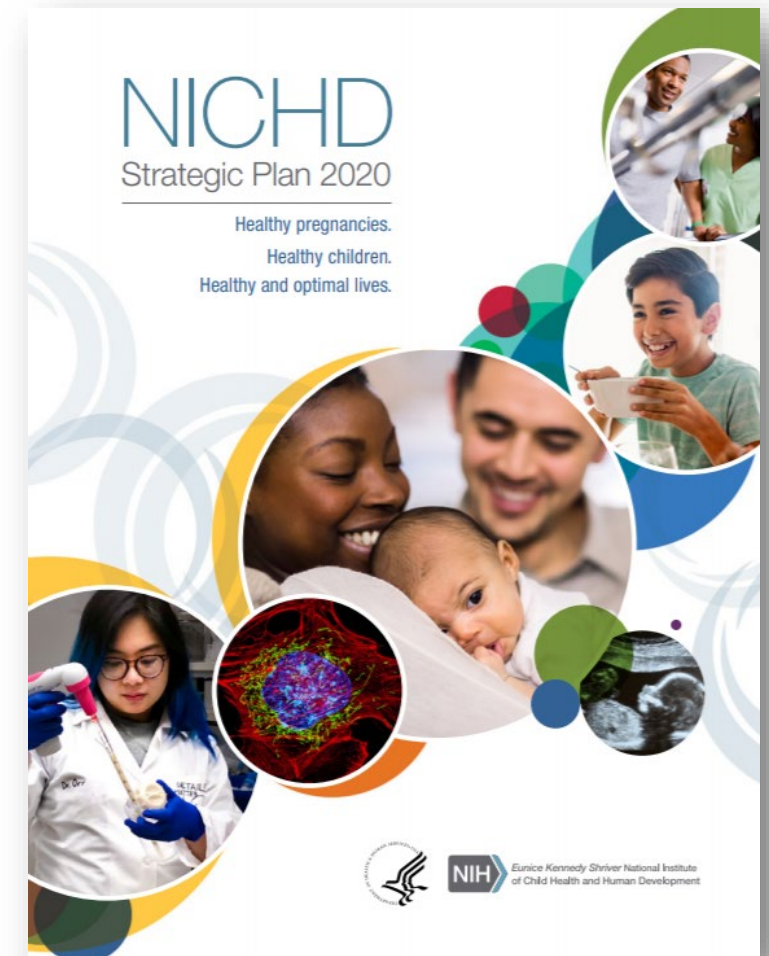
- Diversity/Training
- Data Sharing/ Data Science
- Partnerships
- Prioritization
- Governance
- Clinical Research Oversight
- Reporting and Program Evaluation
- Communications and Legislation

## Management and Accountability



### Goals

- Workforce Development and Balance
- Infrastructure Innovation
- Administrative Efficiency
- Enterprise Risk Management



# Strategic and Implementation Plan Structure

This is an example from the **2020-2025 strategic and implementation plans** – the refresh is maintaining the same structure as the current plan.

The research **objective level has been the primary focus of updates** thus far

**Focus Area:** Scientific Research

**Goal:** Advancing Safe and Effective Therapeutics and Devices for Pregnant and Lactating People, Children, and People with Disabilities

**Objective:** Support clinical research to test and evaluate therapeutics and medical devices used by pregnant and lactating women, children, and people with intellectual and physical disabilities.

**Initiative:** Improve NICHD's clinical research infrastructure, emphasizing networks for drug/device trials and incorporating drug/device trials into broader clinical study networks (e.g., MFMU, NRN).

**Activity:** Through the Pediatric Trials Network, conduct rigorous studies to bolster the scientific evidence base for pediatric drug labeling and use.



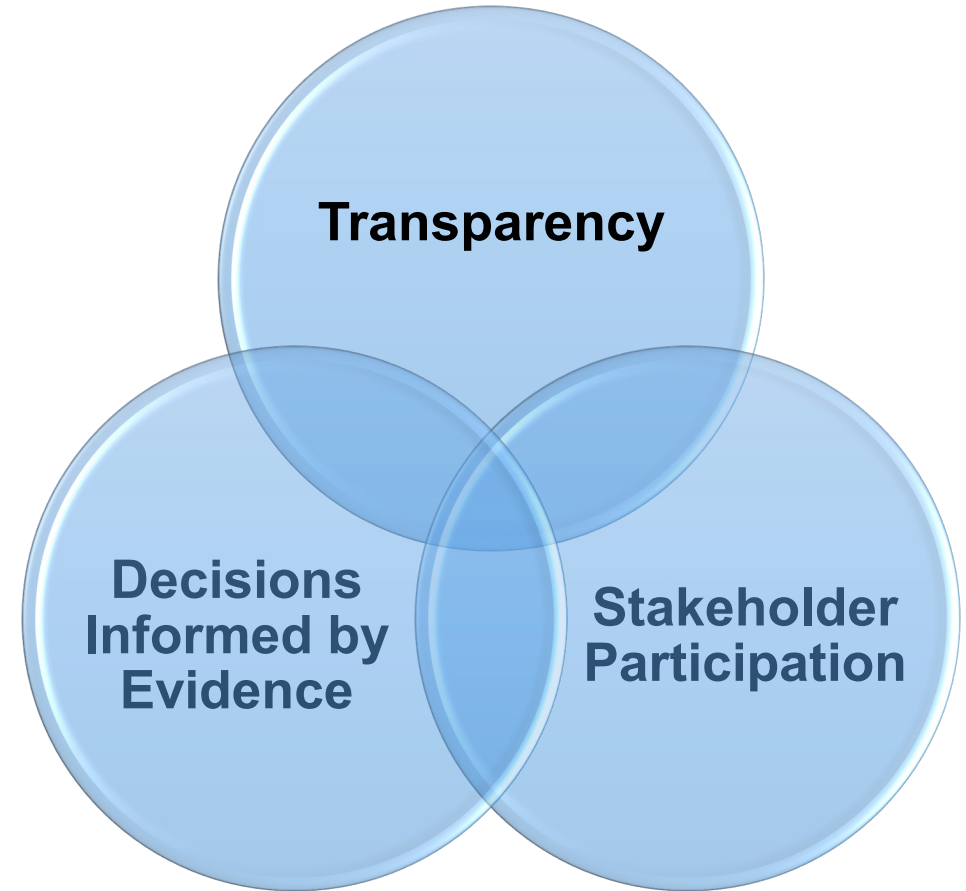
# NICHD Strategic Plan Refresh

## Goals

1. Identify where NICHD should lead (priorities)
2. Identify where NICHD should partner and collaborate
3. Inform future investments in research, training, and infrastructure



## Core Principles



# Strategic Plan Refresh – Transparency



## Collaboration with NICHD staff

- NICHD Lead Effort
- Branch chiefs, intramural leaders, and OD Office directors **formed working groups:**
  - Each scientific research goal (5)
  - Scientific Stewardship (1)
  - M&A (1)
- Internal working groups generated the ideas





# Strategic Plan Refresh - Decisions Informed by Evidence

NICHD working groups were created to lead the refresh process and have spent the last five months considering updates to the scientific research objectives and aspirational goals.

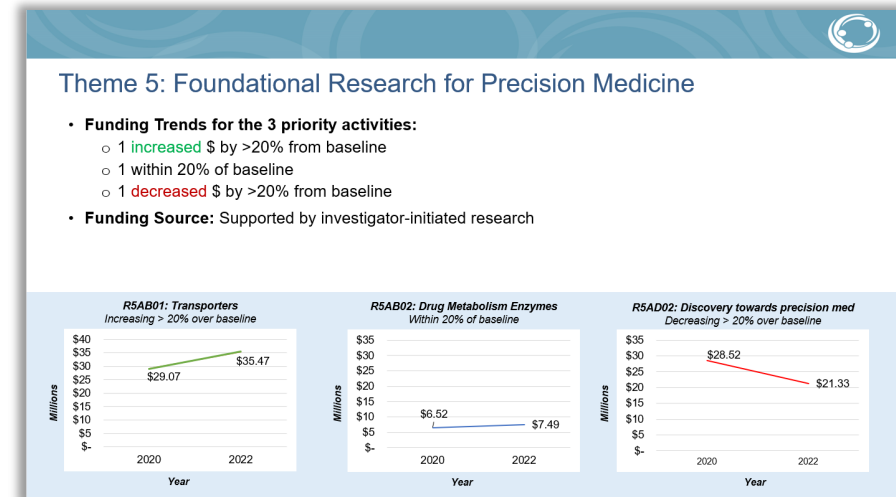


Detailed review of implementation plan reporting analysis



*Specifically, each working group received...*

- Information on the timelines of **major programs/ FOAs** that support the implementation plan
- **Funding trends** on research initiatives and activities
- Information on **cross-cutting theme representation** in the goal, including well-represented areas and opportunity areas to explore



# Strategic Plan Refresh – Stakeholder Participation



External listening sessions with targeted feedback on draft objective concepts

## Listening Session Structure Overview

Each of the listening sessions followed the same structure to allow equal opportunities for feedback and discussion during the virtual sessions.



### Listening Session Structure

- In each session, scientific research working group members\* presented concepts within their goal for discussion among external attendees.
  - Participants were presented with concepts in lieu of the verbatim objectives to encourage active discussion without focus on specific wording used.
  - Concept champions facilitated discussions based on questions that working group members drafted in advance of their respective session.
- External participants had the opportunity to ask clarifying questions and **suggest areas of emphasis** for inclusion.
- Participants were also asked to share **additional topics** they felt were not already represented within the goal, including **moonshot goals**.



RFI Publication, NICHD Council Feedback

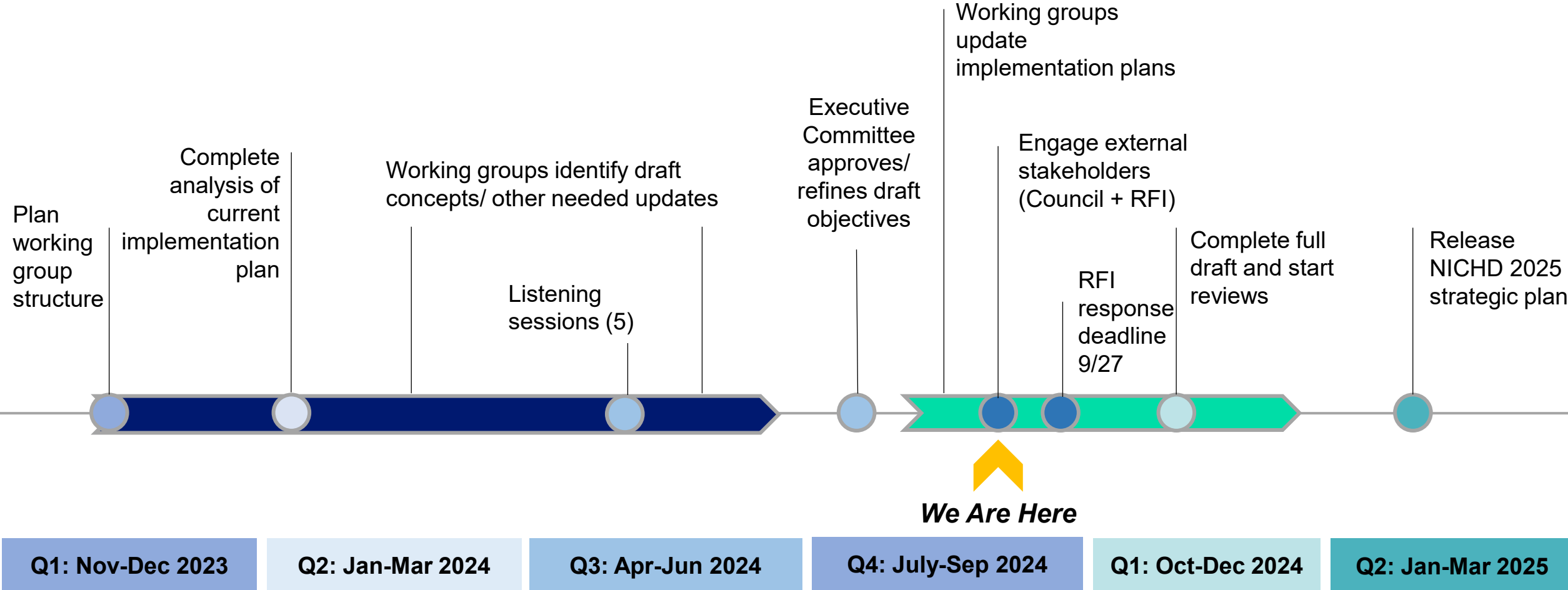
## Agenda

|   |   |                                   |
|---|---|-----------------------------------|
| 1 | Opening Remarks   | 5 mins                            |
| 2 | Introduction  | 5 mins                            |
| 3 | Presentation & Discussion of Concepts for Refreshed Scientific Priorities | 55 mins<br>(~13 mins per concept) |
| 4 | Additional Commentary from Participants                                   | 20 mins                           |
| 5 | Next Steps & Closing  | 5 mins                            |





# Strategic Plan Refresh – Timeline

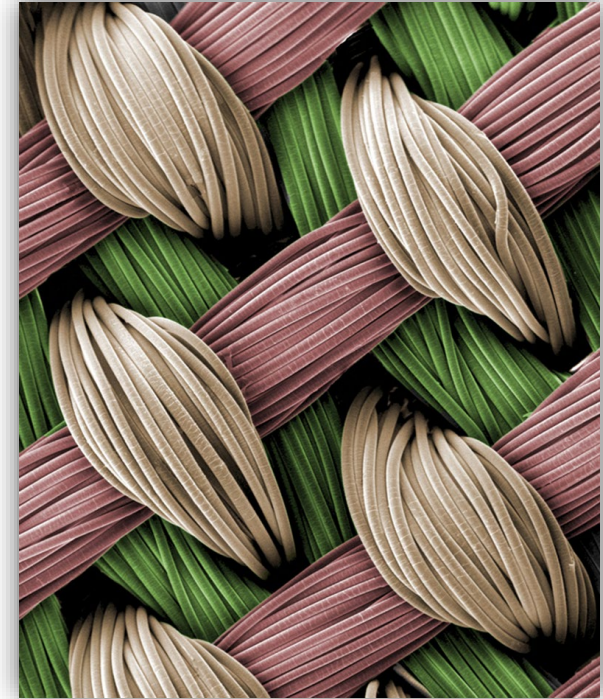




# **Review Draft Refreshed Research Objectives**

# Cross-Cutting Themes

1. **Global Health:** Improve pre-pregnancy health globally using new interventions to benefit pregnancy outcomes, and prevent prematurity, malnutrition, childhood stunting, disease, and developmental delays.
2. **Health Disparities:** Understand how social, economic, structural, and regional factors are vital to the advancement of preventive, diagnostic, and intervention efforts.
3. **Prevention:** Prevent adverse health outcomes, improve early detection, and understand the optimal timing of prevention efforts.
4. **Nutrition:** Improve our understanding of the lifetime impact of nutrition on reproductive health, fertility, pregnancy, and fetal, child, and adolescent growth and development.
5. **Infectious Disease:** Improve the basic understanding of how infectious pathogens affect NICHD populations, address their impact on overall health, and advance safe and effective treatments.
6. **Research Training:** Training and career development of the next generation of the scientific workforce.



Credit: Guilak Lab, Washington University



# Goal 1: Understanding the Molecular, Cellular, and Structural Basis of Development

- A. Improve understanding of the mechanisms underlying developmental processes by elucidating the *intrinsic* factors (such as genetic, epigenetic, molecular, cellular, metabolic, and biomechanical) that contribute to pre- and post-natal development.
- B. Explore how *extrinsic* factors (such as prenatal and perinatal insults, metabolic and nutritional deficiencies, environmental factors, infection, and early injury and disturbances) influence developmental and physiological processes, particularly in the context of addressing congenital anomalies, neurodevelopmental disorders, and intellectual and developmental disabilities.
- C. Enhance collaborative developmental biology research by investing *in improved infrastructure*, along with *tools and technologies*, to analyze and validate large-scale data derived from model systems research and emerging scientific areas.
- D. Use *single-cell genomics, proteomics, and metabolomics* to profile gene and protein expression and regulation and to characterize regulatory networks across tissues and time during development.



## Goal 2: Promoting Gynecologic, Andrologic, and Reproductive Health (1)

- A. Improve *understanding of reproductive stages across the life cycle*, with particular emphasis on typical and atypical initiation, timing, and symptomatology of critical windows such as puberty, andropause, and perimenopause.
- B. Characterize reproductive aging and *its impact on reproductive, andrologic, and gynecologic outcomes*, particularly infertility and the health of children born to older parents.
- C. Identify biologic and environmental factors that can lead or contribute to *idiopathic infertility*. Apply this knowledge to expand technologies or methods for fertility stimulation, fertility preservation, and contraception.
- D. Identify biologic mechanisms underlying how gynecologic conditions (including endometriosis, fibroids, vulvodynia, others) result in *generalized and pelvic pain*.



## Goal 2: Promoting Gynecologic, Andrologic, and Reproductive Health (2)

- E. Identify interventions for *treatment of gynecologic conditions*, such as endometriosis, fibroids, pelvic floor disorders, gynecologic pain, PCOS, and others. Assess the impact of new and existing treatment approaches on gynecologic health disparities.
- F. Improve understanding of the *multi-level factors affecting contraceptive use* and non-use and preferences for specific methods. Apply this knowledge in developing new and improved contraceptive options for both men and women and designing interventions to improve access to and use of preferred methods. Advance knowledge about the *effects of contraceptives on human health*, including their effectiveness as treatments for health conditions





## Goal 3: Setting the Foundation for Healthy Pregnancies and Lifelong Wellness (1)

- A. Capitalize on *interdisciplinary collaborations* to advance knowledge of the mechanisms and potential causes of *preterm birth* and to develop prevention approaches.
- B. Improve the long-term outcomes of infants born preterm or with aberrant fetal growth by understanding the *roles of maternal and paternal factors, social determinants of health, environmental and nutritional factors*, and early interventions.
- C. Integrate and analyze *diverse types of data* (such as genomic, social and behavioral, and/or exposure data) to inform interventions for adverse maternal conditions and complications of pregnancy. Support *community-informed research* to develop maternal health interventions that are widely applicable, with an emphasis on populations experiencing health disparities.



## Goal 3: Setting the Foundation for Healthy Pregnancies and Lifelong Wellness (2)

- D. Use innovative *basic and translational science* approaches to further *understand the placenta*, including its role in pregnancy outcomes and in the long-term health of the mother and infant. Continue to develop technologies and methods for *human placental models* across gestation and test the ability of emerging technologies to assess placental health.
- E. Develop prevention strategies for *labor and delivery complications* that contribute to maternal morbidity and mortality
- F. With an emphasis on populations that experience health disparities, identify new approaches to *mitigate maternal and paternal risk factors for conditions associated with pregnancy* with effects that extend through the postpartum period and beyond.



## Goal 4: Improving Child and Adolescent Health and the Transition to Adulthood (1)

- A. Identify and assess *risk-reduction strategies* to address the systemic, as well as individual, causes of infant mortality domestically and globally. Identify potential approaches to *prevent stillbirth, SIDS, and SUID*.
- B. Determine how *social and environmental factors* affect infant, child, and adolescent health and use this knowledge to develop new and improve the effectiveness of early intervention approaches.
- C. Develop and assess prevention, treatment and implementation strategies to address *trauma, injury (unintentional and intentional), and violence, along with disaster preparedness and response*. Advance research and research training across the continuum of care to optimize recovery of children and families who experience critical illness or traumatic injury.



## Goal 4: Improving Child and Adolescent Health and the Transition to Adulthood (2)

- D. Increase understanding of physical, cognitive, social, and emotional development across the *early lifespan* (infancy through adolescence) to *optimize timing of interventions* for healthy development.
- E. Conduct research to support better *integration of pediatric and adult systems of care, especially for youth transitioning to adult healthcare*. Develop measures that help determine successful transition, at the individual, provider, or system level, to improve care for adolescents and emerging adults.
- F. Enhance the evidence base for pediatric and adolescent primary care by *identifying practices and features of health care delivery associated with positive child health outcomes*. Support dissemination and implementation research for pediatric prevention strategies with demonstrated efficacy, including in health disparity populations.



## Goal 5: Advancing Safe and Effective Therapeutics & Devices for Pregnant & Lactating People, Children, and People with Disabilities

- A. Conduct and support foundational research on the development of interventions targeted to the specific needs of pregnant or lactating people, children, and/or people with disabilities informed by *pharmacokinetic, pharmacodynamic, pharmacogenomic, dosing, and formulation studies*.
- B. Identify and validate *biomarkers*, modeling approaches, and outcome measures that can be used to support rigorous testing and/or regulatory approval of *pharmacotherapies and devices* in pregnant and lactating people, children, and/or people with disabilities.
- C. Support *clinical research and dissemination and implementation* to evaluate scalable, accessible therapeutics, diagnostics and medical devices for pregnant and lactating people, children, and/or people with disabilities.
- D. Use advanced data science techniques to *assess health outcomes, therapeutic safety or effectiveness, health care engagement, and health care delivery* in datasets that include pregnant and lactating people, children, and/or people with disabilities.





# **RFI Comment Period – Strategic Plan 2025**



# RFI Comment Period: NICHD Strategic Plan 2025

## Request for Information (RFI): NICHD Strategic Plan 2025

### Notice Number:

NOT-HD-24-028

### Key Dates

#### Release Date:

August 28, 2024

#### Response Date:

September 27, 2024

### Related Announcements

None

### Issued by

Eunice Kennedy Shriver National Institute of Child Health and Human Development ([NICHD](#))

### Purpose

The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) is updating its current (2020-2024) strategic plan (<https://www.nichd.nih.gov/about/org/strategicplan>). The updated plan for 2025-2029 will help guide the research NICHD will support over the next five years. The purpose of this Request for Information (RFI) is to solicit feedback on the scientific goals and opportunities under consideration for the refreshed NICHD strategic plan.

### Background

For more than six decades, NICHD has provided both national and international leadership for research involving children, pregnant and lactating people, and individuals with disabilities. In the fields of developmental biology, reproductive health, child development, pediatrics, population health, and medical rehabilitation, the institute's broad research portfolio has advanced the biomedical and behavioral health of our nation.

*What feedback do you have on the scientific research priorities listed in the RFI?*

**RFI**

**Responses due  
9/27/2024**

**RFI Link:** <https://grants.nih.gov/grants/guide/notice-files/NOT-HD-24-028.html>

# Thank You to the Listening Session Participants!

## Goal 1

- Celeste Nelson
- Mustafa Khokha
- Maria Barna
- Crystal Rogers
- Elizabeth Ross
- John Wallingford
- Philip Lupo
- Jessica Whited
- Robert Braun
- Susan Lynch
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## Goal 2

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- Cathy Rice
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- Maged Costantine
- Jonathan Davis
- Willi Horner-Johnson
- Biana Godin
- Irina Buhimschi
- Beth Smith
- Cosmin Bejan



# Thank You to Our NICHD Working Groups!

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- Sonia Lee
- Samantha Calabrese
- Tonja Nansel
- Denise Haynie
- Karen Winer
- Sue Marden
- Susan Jekielek
- Camille Fabiyi
- Perdita Taylor-Zapata
- Vesna Kutlesic

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- Sujata Bardhan
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- Vesna Kutlesic
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- Laura Berkson
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- Marlene Mireles
- Alexis Clark
- Howard Levitas
- Kim Kober
- Charlie Kim
- Jemma Robinson
- Jessica Wu
- Valerie Leftwood
- Francie Kitzmiller



# Thank you for your time!

