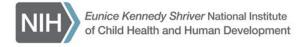
THE NICHD SCIENTIFIC VISION





Caroline Signore, MD, MPH September 18, 2015



Outline

- The Vision process and statement
- Implementing the Vision
 - Emphasis areas
- Sampling of other activities
- Adjustments? Emerging directions? New emphasis areas?



The Visioning Process

2011 Workshops

2012 **Vision Publication**

2013...

Implementation



















NICHD's Scientific Visioning: Purpose

To identify the most promising scientific opportunities of the next ten years across NICHD's mission

To set an ambitious agenda that inspires the NICHD, its partners, and the research community to achieve critical scientific goals and improve health





Eunice Kennedy Shriver National Institute of Child Health and Human Development

Mission & VISION are broad





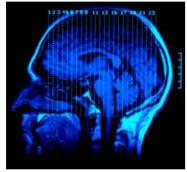












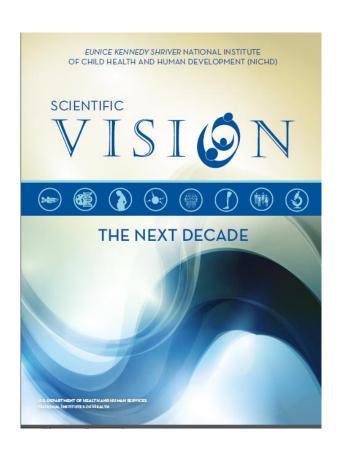


Vision Themes

- Developmental Biology
- Developmental Origins of Health and Disease
- Pregnancy and Pregnancy Outcomes
- Reproduction
- Behavior and Cognition
- Plasticity and Rehabilitation
- Population Dynamics
- Conduct of Science



Scientific Vision: The Next Decade

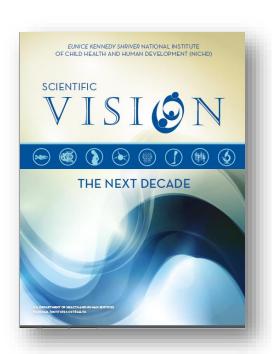


Not a prescription for NICHD activities, but an analysis of promising opportunities that will help inform future directions



Within the next 10 years scientists should be able to...

23 opportunities, including, for example;



Delineate the genetic, epigenetic, and environmental interactions underlying the etiology of at least three major gynecological disorders.

Identify 5,000 genetic variants that influence specific behaviors or cognitive traits.

Develop a range of **robotics** that will enable individuals with developmental or acquired disabilities to obtain or maximize daily function in their home settings.



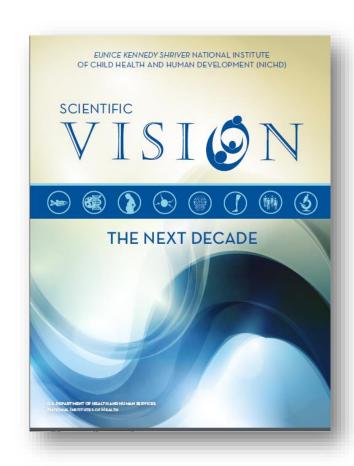
Implementing the Vision: Selection of Emphasis Areas



Selection of Emphasis Areas

NICHD emphasis areas:

- Areas essentially NICHD
- Public health importance
- Scientific opportunity
- Critical for NICHD to undertake
 - "if NICHD doesn't, no one will"





Initial Vision Emphasis Areas FY2014-15

- Develop new methods for intrauterine assessment of placental & fetal function
- Contraception
- Understand long-term Implications of Assisted Reproductive Technologies (ART)



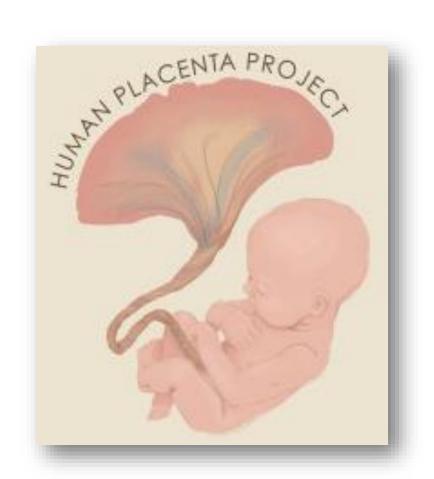
Develop new methods for intrauterine assessment of placental & fetal function

Emphasis Area 1



HPP

Understand placental structure and function in real time





Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH)

Components of Participating Organizations

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

3 RFAs: R01, R21, U01 \$ 46 Million

Funding Opportunity Title

Novel Tools to Assess Human Placental Structure and Function (R01)

Novel Tools to Assess Human Placental Structure and Function (R21)



Department of Health and Human Services Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH)

Components of Participating Organizations

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

National Institute of Biomedical Imaging and Bioengineering (NIBIB)

Funding Opportunity Title

Developing Paradigm-Shifting Innovations for in vivo Human Placental Assessment in Response to Environmental Influences (U01)



National Institutes of Health (NIH)

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) National Institute of Biomedical Imaging and Bioengineering (NIBIB)

In-vivo Methods for Assessing Placental Development and Function (SBIR) (R43/R44)

R43/R44 Small Business Innovation Research (SBIR) Grant - Phase I and Fast-Track

Develop an algorithm to predict placental dysfunction and pregnancy complications from placental morphology measurements obtained via 3D ultrasound early in pregnancy



Emphasis Area 2



NICHD Contraceptive Research Review

- Communication
- Scientific Review
- Behavioral Research
- Funding Mechanisms



NIH – Bill & Melinda Gates Foundation Meeting

• July 8 – 9, 2015

 Contraceptive research breakout session to explore opportunities for collaboration











NICHD Male Contraceptive Research

- Upcoming multisite efficacy trial involving the male CCTN testing Nestorone/Testosterone gel as a novel user-controlled male hormonal contraceptive
- Novel androgen in repeat-dose studies showing promise as a "male pill"



Understand Long-term Implications of Assisted Reproductive Technologies (ART)

Emphasis Area 3



Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH)

Components of Participating Organizations

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

Funding Opportunity Title

Long-Term Outcomes of Medically Assisted Reproduction (R01)



PAR-14-272 (R01) PAR-14-273 (R21)

Next Submission Deadline:

September 30, 2015



Select Pay Vision

Notice of NICHD's Interest in Supporting Research on Contraception, Long-Term Outcomes of Assisted Reproductive Technologies, and Intrauterine Assessment of Placental and Fetal Function

Notice Number: NOT-HD-14-020

Key Dates
Release Date: June 10, 2014



Select Pay Vision FY 2014 - 2015

2014

- R01 Genomics of Spermatogenic Impairment
- Next generation screening to identify single gene defects associated with spermatogenic failure

2014

- R21 New Player in Placental Dysfunction: miR210
- Hypothesize that miR-210 is an important mediator of adverse pregnancy outcomes

2015

4 applications nominated



Selected Updates on the Broader Vision and the 23 Opportunities



Process to date

- High-level analyses of the 23 opportunities to:
 - Identify NICHD-funded activities that are both specifically and thematically relevant
 - Identify relevant activities of other ICs
 - Summarize relevant recent publications
- NICHD scientific staff comments sought on:
 - Results of analyses
 - Vision areas of emphasis: Reconsider/revise? New opportunities? Next steps?



Assessment questions for each Opportunity

 Briefly outline any NICHD activities and/or the scientific community's activities to help move toward achieving this part of the Vision.

 Have other needs or opportunities arisen within this broad Vision theme that should be higher priority than this example? If yes, what are they and why?



Theme: Developmental Biology

Opportunity: build a **comprehensive guide** to molecular pathways and genomic/epigenetic regulation of **developmental defects**

- Single-cell developmental atlas in worm models (Santella, 2015)
- Technique for completing genome-wide profiles of single cells more quickly (Makosco, 2015)



Theme: Developmental Biology

Opportunity: Construct a library of pluripotent cells

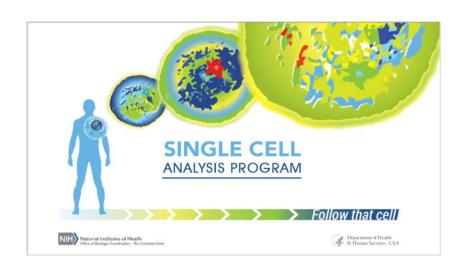
- Key task is developing reproducible protocols for generating a variety of cell types from induced pluripotent stem cells
- Perfect protocols for generating iPSCs
- NICHD established Stem Cell Interest Group



Theme: Reproduction

Opportunity: Characterize both female and male single germline cells

- Common Fund Single Cell Analysis Program
- Major hurdle is purification of specific cell types





Theme: Plasticity and Rehabilitation

Opportunity: Develop a range of **robotics** to enhance daily function of people with disabilities in their home settings

- National Robotics Initiative: NSF, NIH, USDA, NASA, DoD
- NCMRR research includes: improving interfaces between the body and the robot; sophisticated wheelchair controls that autonomously move the user when necessary
- NOT-EB-14-008: development of assistive robotic technology to achieve functional independence in humans; improve quality of life; assist with behavioral therapy and personalized care; and promote wellness/health.



Theme: Conduct of Science

Opportunities:

- Develop biorepositories
- Change the predominant model for data use to one of open access

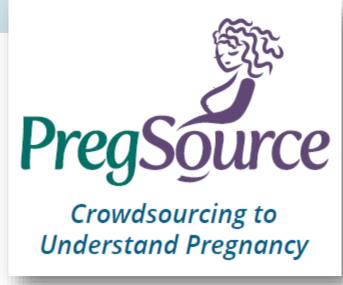






Theme: Conduct of Science

Opportunity: **Involve the public** in better reporting, identification, and definition of normal life processes, including pregnancy, child development, and adolescence





Areas under continuing development

- Identifying causes of stillbirth and preterm birth
- Determining risk and impact of concussion injuries
- Identifying bases and biologic markers of behavioral disorders
- Identifying causes of autism spectrum disorders
- Genetic and epigenetic interactions and gynecological disorders
- Male and non-hormonal contraception
- Health care and independent living options for persons with disabilities



Longer term aspirations

- Exposome and neuroplasticity
- Multigenerational cohorts
- Developmental neuroplasticity





Eunice Kennedy Shriver National Institute of Child Health and Human Development

Mission & VISION are broad





Questions for Council Discussion

Vision Themes

- Developmental Biology
- DOHaD
- Pregnancy and Pregnancy Outcomes
- Reproduction
- Behavior and Cognition
- Plasticity and Rehabilitation
- Population Dynamics
- Conduct of Science

New opportunities?

New or additional areas of emphasis?



- Early exposures and health/developmental outcomes
 - Identify 10 most important exposures/predictors of age-related decline, excess morbidity and mortality
 - Move beyond associations and develop interventions
 - Nutritional interventions in pregnancy
 - Optimal biopsychosocial intervention strategies in the "first 1000 days" to promote healthy development and resilience and prevent the early onset of chronic diseases or conditions



- Role of the microbiome in reproduction and child development
- Facilitate natural history studies of rare conditions identified in the newborn period by collaboratively establishing core and common data elements for use across institutes and Federal Agencies



- Develop gene regulatory networks for early developmental stages [embryogenesis: from fertilization through preimplantation development, implantation, gastrulation to formation of organ primordia]
- Apply a systems biology approach to intellectual and developmental disabilities



- Assess the safety and effectiveness of new pharmacotherapeutics for pregnancy induced/related conditions/diseases
- Evaluate models of rehabilitation interventions that consider the timing, intensity and duration of intervention and establish optimal delivery schedules and amount of intervention for patients in different diagnosis categories



Thank together evelopment you! achieve anniversary Beyond workshops **Visionbroad ute** identifying science decade 50 directions National