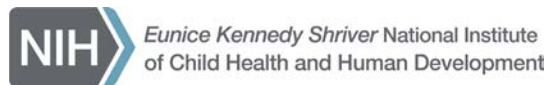


Extending NICHD's Work Through Partnerships

Lisa Kaeser, J.D.

Director, Office of Legislation and Public Policy

January 23, 2020





What Kinds of Partnerships May NICHD Engage In?

Authority to enter into collaborations: 42 U.S.C. § 282 et seq:

- NIH Director shall:
 - Take “advantage of collaborative, cross-cutting research”
 - Encourage collaborations to allow “increases in the number of subjects studied,” and
 - “utilize diverse study populations”



Idea for a Collaboration or Partnership?

First Ask:

- Would this further NICHD's mission?
- Would the collaboration allow NICHD to do something the institute could not do otherwise?
- Is NICHD's role, and that of the partner(s) clearly defined?
- What are the costs, if any?
- Has the concept or draft been vetted with NICHD leadership?
- Does the timeline required for drafting the agreement and approval work for the project?

NICHD Engages in a Wide Range of Collaborations

- Agreements may depend on the type of organization
 - Trans-NIH (Maternal Mortality, Down syndrome)
 - Interagency
 - Other federal agencies (e.g. FDA, CDC, HRSA, DoD)
 - Outside Organizations
 - Nonprofit (Professional societies, 501(c)3 organizations, foundations, universities)
 - For profit (PhaRMA, industry)
- Not all need formal documentation



Agreements Can Take Many Forms, including:

- Tech Transfer
 - Material Transfer Agreements
 - Cooperative Research and Development Agreements
 - Clinical Trial Agreements
 - Generally no exchange of IP
- Gifts – donations and bequests
- Contractual agreements
- Personnel agreements/details
- Not a back-door way for an unsuccessful grant applicant to get NIH funding



Gifts and Donations

🔄 nichd.nih.gov/about/partner_donate/donating

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Donating to NICHD

NICHD is a research agency of the federal government funded by congressional appropriations. It does not solicit funds or participate in fundraising activities, but is authorized by Congress to accept gifts and bequests of money or personal property for the purpose of carrying out its activities, pursuant to Sections 231 and 405 of the Public Health Service Act, as amended.

Acceptance of any gift is a discretionary administrative decision based on program needs and public policy considerations. NICHD is able to accept most gifts, as long as any conditions of the gift are not illegal, contrary to public policy, or burdensome, and as long as accepting the gift would not create a real or apparent conflict of interest.

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Many Types of Collaborations

- Research endeavors
- Committees, Advisory Groups, Working Groups
- Meetings, Conferences, Workshops
- Public Education Campaigns
- Training Initiatives



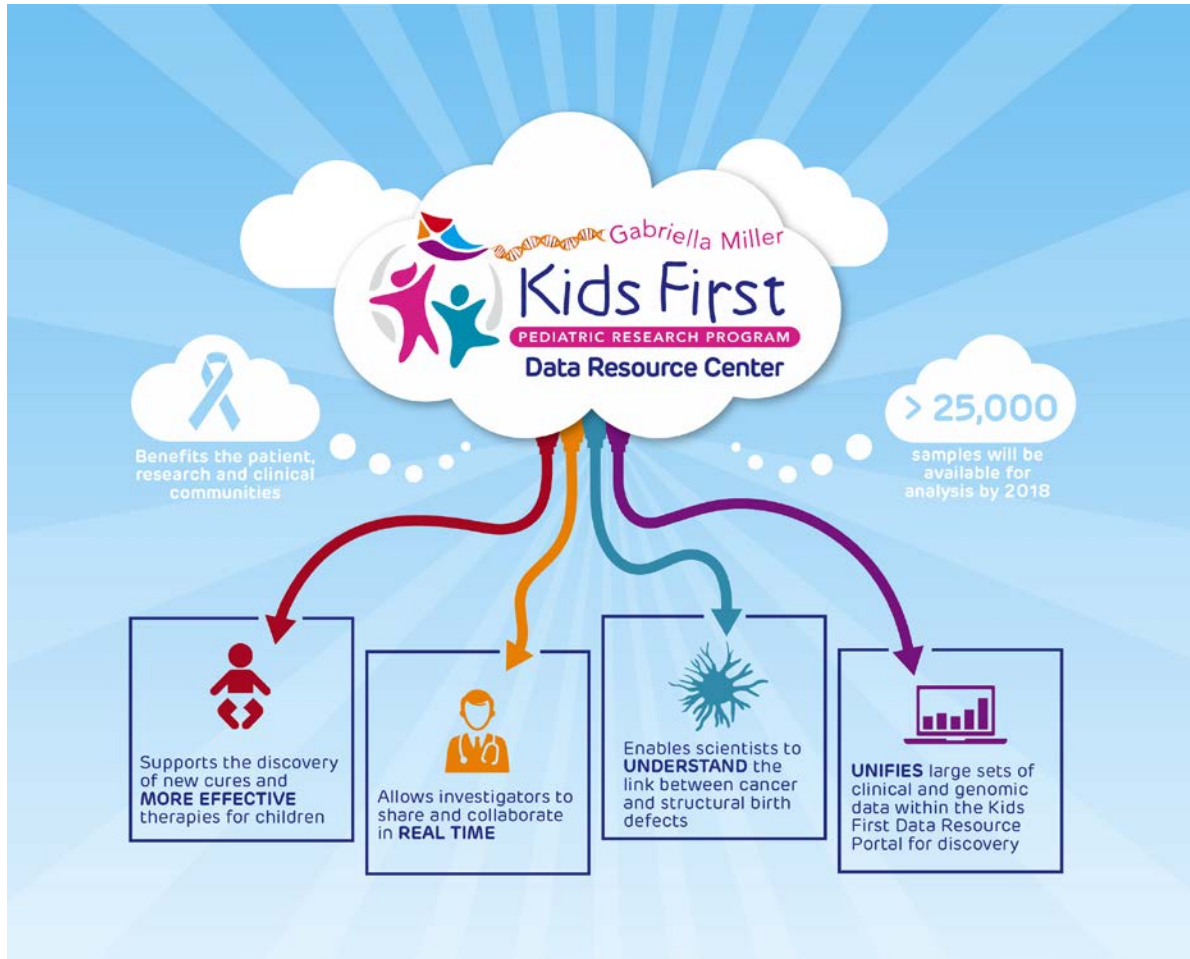
NICHD Collaborations: Trans-NIH and Interagency

- Autism
- Birth defects
- Down syndrome
- Fragile X
- Muscular dystrophy
- Fetal alcohol syndrome
- Injury prevention
- Child maltreatment
- HIV/AIDS
- Obesity
- Child health statistics
- Early Learning
- Pediatric pharmacology
- Pregnancy and medication
- Maternal health/mortality
- Medical rehabilitation
- Prosthetics
- Traumatic brain injury
- Preterm birth
- Disaster response
- Substance misuse/NOWS
- Nutrition
- Rare diseases
- SIDS/SUID
- High risk teen behavior
(including substance abuse,
driving, teen pregnancy, others)
- Zika



Gabriella Miller Kids First Pediatric Research Program (Kids First)

- NIH Common Fund Program



NIH Pediatric Research Consortium (N-PeRC)

NIH Pediatric Research Consortium (N-PeRC)

- Overview
- N-PeRC Members
- More Information

Overview



N-PeRC is a trans-NIH initiative that began in June 2018 to capitalize on pediatric research expertise and resources across NIH's 27 institutes and centers through increased collaboration. The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) is the lead NIH institute for the consortium.

NIH support for pediatric research currently totals more than \$4 billion. N-PeRC aims to harmonize these activities across institutes, explore gaps in the overall pediatric research portfolio, and share best practices to advance science. The consortium meets several times a year to discuss scientific opportunities and potential new areas of collaboration, including efforts to enhance research training for the next generation of pediatricians.

- Nearly all of the NIH ICs fund some aspects of child health research

<https://www.nichd.nih.gov/research/supported/nperc>



NICHD Collaborations: Federal Agencies, 2016-2019



- Census Bureau
- CPSC
- Dept. Agriculture
- Dept. Defense
- Dept. Education
- Dept. Justice
- Dept. Transportation
- EPA
- HUD
- NEA
- NEH
- NSF
- OMB
- ONDCP
- SSA
- USAID
- HHS
- ACF
- ACL
- AHRQ
- ASPE
- ASPR
- ATSDR
- CDC
- FDA
- HRSA
- IHS
- OASH
- OGA
- SAMHSA
- President's Council on Fitness, Sports, and Nutrition

DoD-NICHD Limb Preservation and Loss Registry

MEMORANDUM OF AGREEMENT

Between the

*EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD
HEALTH AND HUMAN DEVELOPMENT of the NATIONAL
INSTITUTES OF HEALTH*

And the

*U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND, CLINICAL
AND REHABILITATIVE MEDICINE RESEARCH PROGRAM of the
DEPARTMENT OF DEFENSE*

To Establish the DoD-NICHD Limb Preservation & Loss (LP&L) Registry

I. Purpose

This Memorandum of Agreement (MOA) between the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) and the United States Army Medical Research and Materiel Command (USAMRMC), Clinical and Rehabilitative Medicine Research Program (CRM RP), describes the joint NICHD/USAMRMC initiative, “DoD - NIH Limb Loss Registry.”



NICHD Collaborations: Public-Private Partnerships

- Memorandum of Understanding (MOU) captures roles and responsibilities of partners:
 - Must further the mission of NICHD
 - Shared goals – leverage knowledge, skills, resources, and services
 - Signed off and agreed to by each partner
 - Time limited



What is included in a MOU?

- A statement that describes how the activities align with NICHD's mission
- Specific roles/obligations for which each party will be responsible
- Effective and end dates, and a way to measure progress
- All partners' points of contact
- Usually signed by the NICHD Director or EO and counterparts at other organization(s)



Mars Corporation/Waltham Centre

- Supports research on Human-Animal Interaction
- Helped establish/grow this nascent field
- by supporting workshops, funding
- opportunities
- Numerous publications to date:
 - Adolescents with type 1 diabetes became more
 - disciplined about checking blood glucose when they
 - started caring for pet fish
 - Children on the autism spectrum were found to be calmer when playing with guinea pigs, and improved social interaction after these sessions

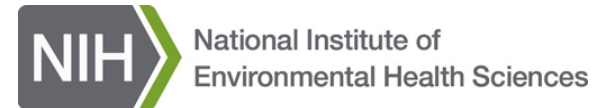
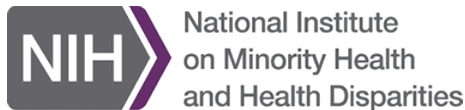
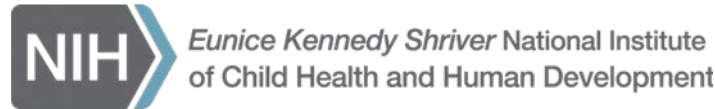


Multi-faceted Partnership: PregSource®

- A crowd-sourced, interactive, platform to:
 - Detail the natural history – and variations – of human pregnancy
 - Provide accurate info about pregnancy from trusted sources
 - Let pregnant women know about opportunities to participate in targeted research
- 20 partner organizations



PregSource[®] Partners



All of Us Launches Pilot Project to Engage Pregnant Participants

- November 14, 2019
- **Collaboration with NICHD's PregSource to Yield New Insights on Pregnancy**

The All of Us Research Program is pleased to announce a collaboration with NIH's Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) on a new pilot project, inviting eligible participants to join [PregSource](#), a separate research effort to gather information about pregnancy.



Partnerships Through the Foundation for the NIH (FNIH)

- Established by Congress as a 501(c)(3) organization (i.e. not part of NIH) in 1990
- Purpose: to support mission of NIH
- Not subject to government policies and regulations regarding funding
- Administers research programs, supports education/symposia, and forms PPPs with donors (public and private)
- Rarely do formal partnerships involve less than \$50K
- Example: Alzheimer's Disease Neuroimaging Initiative (ADNI) – aimed at speeding clinical trials by providing researchers with biomarkers



FNIH Application Process (6-8 weeks)

- Application form must be submitted to OD/OSP
- Includes goals, milestones, potential partners and level of involvement, detailed budget
- Helpful to have budget office review
- IC director must sign
- OSP review
- FNIH Steering Committee review
- OGC review



FNIH Application Process (cont.)

- FNIH PPP Committee conducts “feasibility study” with a few potential donors
- Recent events indicate caution
- If project accepted, FNIH raises funds within 9 months – one year
- PPP fees on sliding scale (3 % – 15%)
- Events/symposia – set fee
- Costs borne by non-NIH sponsor
- <https://osp.od.nih.gov/policy-reporting/nih-staff-initiated/>



Future Partnerships to Enhance Science: NICHD's Strategic Plan

- NICHD will continue to enter into a range of agreements to augment and strengthen its science with:
 - Other NIH ICOs and federal agencies
 - Nonprofits and industry
 - Professional societies
 - Foundations





Questions?