

# Trans-NIH Pediatric Research Initiatives

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# TWO SEPARATE FUNDS FOR PEDIATRIC RESEARCH

Fiscal Year 2015 appropriation to NIH contained two noteworthy items for the pediatric research community:

- It appropriated funds in the Common Fund in response to the Gabriela Miller Kids First Act
- Provided additional flexibilities to the NIH related to the National Children's Study. Dr. Tabak will describe these to you.

## Common Fund Pool – Gabriella Miller Kids First

- \$126 Million over 10 years
- Must meet CF criteria

# Pediatric Research in the Common Fund:

## How did we get here?

### Gabriella Miller Kids First Research Act: Signed into law on April 3, 2014

- Named for Gabriella Miller, a 10 year old who died of cancer; prior to her death, she called on Congress to take action on pediatric research
- Ends taxpayer contribution to presidential nominating conventions
- Transfers this money into the 10 Year Pediatric Research Initiative Fund; **authorizes** \$12.6 million out of the Fund each year for pediatric research through the Common Fund
- Prohibits use of these funds for any purpose other than making grants for pediatric research described in the Act

### FY 2015 “Cromnibus” Funding Bill: Signed into Law **December 16, 2014**

- Appropriated \$12.6 million to the Common Fund for pediatric research, as authorized in the Gabriella Miller Kids First Research Act
- Implication is that this money will recur (10 years)
- Must meet CF criteria, align with CF vision/purpose

# What do we look for in a Common Fund program?

**Transformative:** Programs are expected to have **exceptionally high and broadly applicable impact**. They should be relevant to many diseases and many ICs. They should create entirely new approaches to research or clinical care, or establish new biological paradigms.

**Catalytic, Short Term and Goal-driven:** Programs must achieve - not just work toward - a goal. They have **deliverables** - data sets, tools, technologies, approaches, or fundamental principles of biology, etc – that can be achieved within **5-10 years**. If the deliverable is expected to have ongoing maintenance costs, a vision for transition and sustainment must be articulated.

**Synergistic /Enabling:** Programs should be **value-added to the ICs**, with the output enabling the mission of multiple ICs.

**Requires a High Level of Trans-NIH Coordination:** CF programs should address complex issues that require trans-NIH teams, insights and perspectives to design and manage. There must be a **reason why strategic coordination is required**.

**Novel:** Programs should provide **new solutions to specific challenges**. If similar efforts exist, the CF program should be tightly coordinated to prevent duplication of effort. *Programs should not be something another entity would be likely to support.*

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**Designed to accomplish goals and deliverables within 5-10 years**  
**Evaluation of program outputs/outcomes is essential**

# Gabriella Miller Kids First Planning Process

- A trans-NIH Working Group was established to consider the challenges and opportunities for transformative pediatric research.
  - The group was asked to consider strategic planning activities that may have occurred via IC activities. COULD INITIATIVES THAT WERE SUGGESTED THROUGH THOSE ACTIVITIES BE ADJUSTED OR ENHANCED TO MEET THE CF CRITERIA?
  - The group met January 6 and coalesced around the need for data: **Build the capability to integrate data from multiple IC-funded pediatric cohorts.**
    - Provide support for genotyping and possibly other data acquisition to participating cohorts; cohorts would provide phenotypes, exposure data, or other info
    - Establish computational infrastructure and support for a pediatric data resource
    - Support demonstration projects that illustrate the utility of this approach
- A small group of IC Directors met on January 20 and endorsed this idea while acknowledging that additional input is needed.

## NEXT STEPS:

- ***Input from the community will be required to consider this and possibly other concepts.***
  - What are the possible use cases of integrated pediatric datasets?
  - How would this program relate to other data resources and/or other pediatric-specific programs?
  - Are there other opportunities for transformative impact in pediatric research that should be considered?
- Discussion with NIH Leadership will occur in Spring, 2015 to determine how funds in FY15 and beyond will be spent.

## Council of Councils – Jan 30, 2015

- Extending data from existing cohorts and establishing an integrated data resource
  - Enthusiasm?
  - Concerns?
  - Suggestions?
- Other thoughts?
- Options for Fiscal Year 2015:
  - Jumpstart a coordinated pediatric data program through supplements to existing awards
  - Supplement existing Common Fund awards for diverse pediatric research objectives while launching an extended planning process for a nine year coordinated program