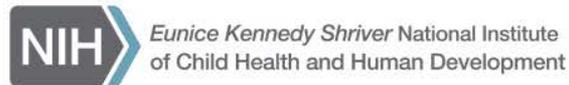# Division of Extramural Research Update

September 13, 2018

Della M. Hann, Ph.D.
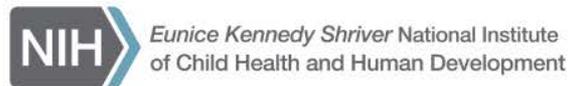
Overview

- Supporting the Researcher Pipeline

- Progress in Clinical Trial Reforms

- Staff Updates

Supporting the Researcher Pipeline

Congressional Input

CONGRESS.GOV | Legislation

H.R.34 - 21st Century Cures Act

114th Congress (2015-2016) | Get alerts

Subtitle C—Supporting Young Emerging Scientists

SEC. 2021. INVESTING IN THE NEXT GENERATION OF RESEARCHERS.

(a) IN GENERAL.—Part A of title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended by adding at the end the following:
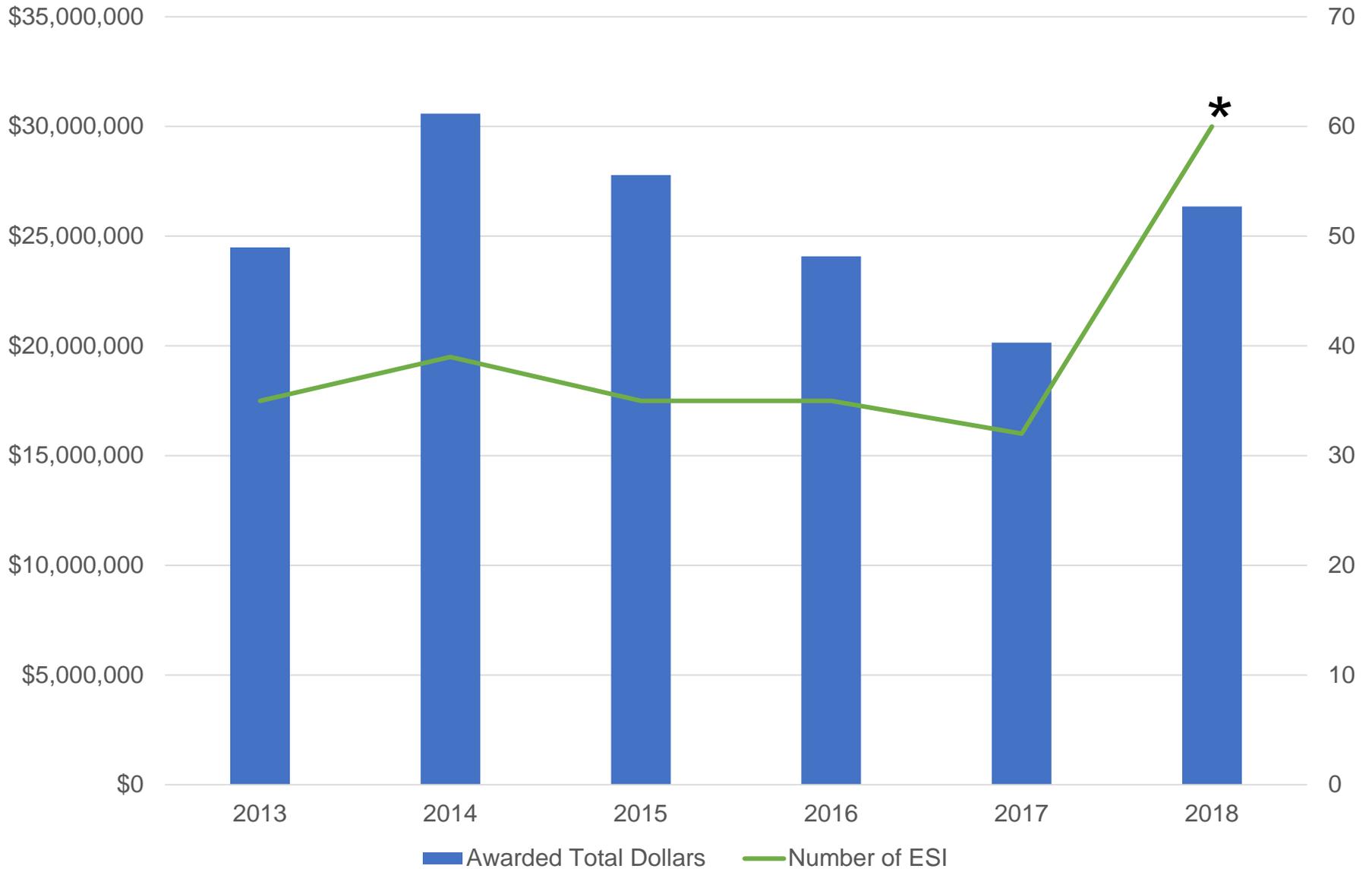
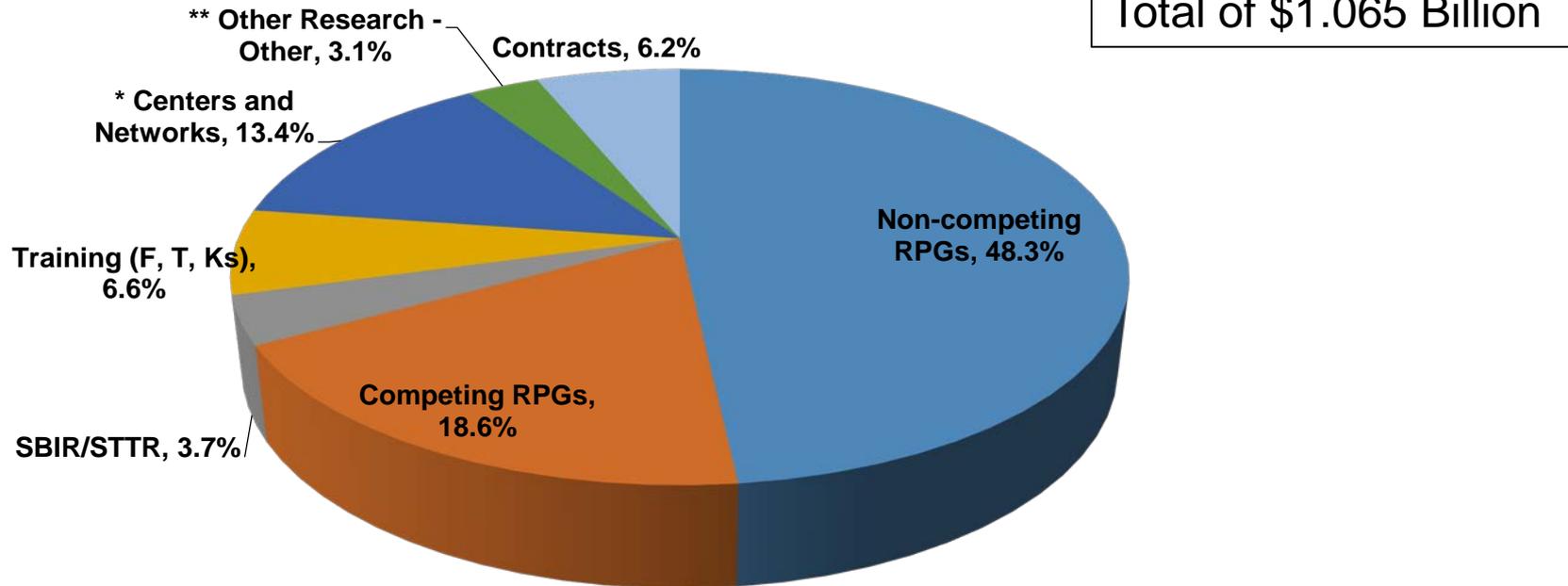"SEC. 404M. NEXT GENERATION OF RESEARCHERS.

What the Law Calls For

"The Director of the National Institutes of Health shall … develop, modify, or prioritize policies, as needed … to promote opportunities for new researchers and **earlier research independence**, such as policies **to increase opportunities for new researchers** to receive funding, enhance training and mentorship programs for researchers, and **enhance workforce diversity**."
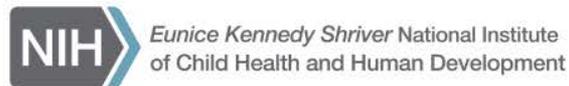
Early Stage Investigators (ESI)

Legend: Awarded Total Dollars (blue bars), Number of ESI (green line)

*FY2018 data is estimated

FY2017 NICHD Appropriations - Extramural only

** Other Research - Other, 3.1%

Contracts, 6.2%

* Centers and Networks, 13.4%

Training (F, T, Ks), 6.6%

SBIR/STTR, 3.7%

Competing RPGs, 18.6%

Non-competing RPGs, 48.3%

Total of $1.065 Billion

*   Select contracts supporting networks included in Centers and Networks
** Other Research – Other: G11, U13, R13, R24, R25, P2C, U24 and T15 (and others)
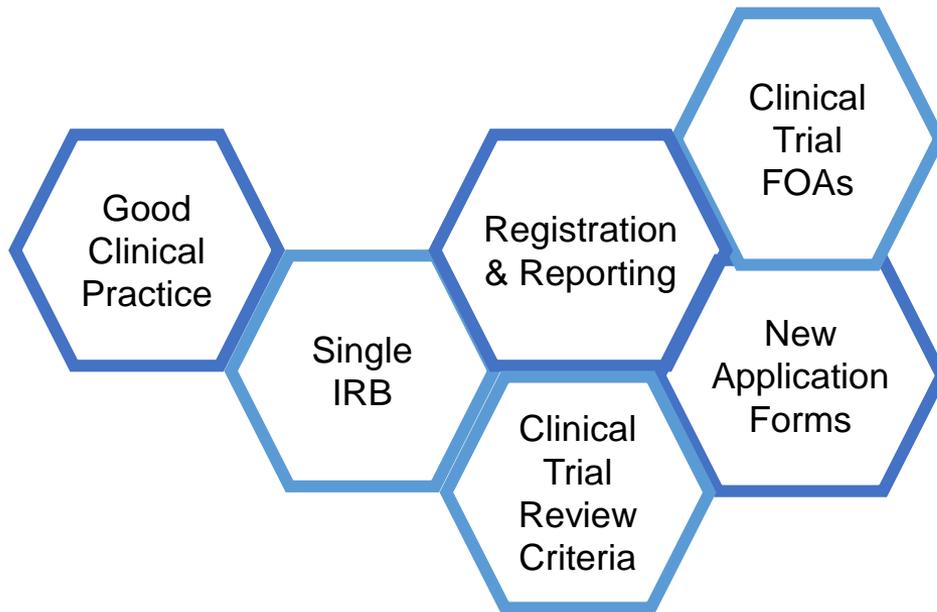
Update on NIH Clinical Trials Efforts

NIH > Eunice Kennedy Shriver National Institute
of Child Health and Human Development

Meredith D. Temple-O'Connor, Ph.D.
Senior Policy Advisor for Clinical Research

NIH Initiatives to Enhance Clinical Trial Stewardship

Good Clinical Practice

Single IRB

Registration & Reporting

Clinical Trial FOAs

New Application Forms

Clinical Trial Review Criteria

Enhancing Clinical Trial Stewardship at NIH

- ✓ Accountability
- ✓ Transparency
- ✓ Efficiency
- ✓ Dissemination

Learn more at https://grants.nih.gov/policy/clinical-trials.htm

Purpose of Reforms & Policy Changes

In 2016, NIH announced initiatives targeted to enhance and improve:

Efficiency

Enhance the efficiency of how research studies involving human participants are conducted

Transparency

Promote a culture of transparency in research in order to advance public health

Accountability

Ensure that NIH can appropriately identify and report on their clinical trials portfolio to ensure proper stewardship

Timely Reporting

Decrease the time it takes investigators to publicly report study results

Status Check

- **NIH clinical trials (CT) policies have been/are being implemented**
- **Important things to know right now**
  - **FOAs and the new form**
  - **NICHD-specific FOAs for investigator-initiated clinical trials**
  - **Monitoring and Oversight Plans**

Monitoring and Oversight of Trials

- **A milestone plan**
  - Different types of information to understand the status of a given trial
  - Goal: Ensure that each trial stays on track
- **Milestone planning and reporting**
  - NICHD staff and investigators work collaboratively on milestone plans
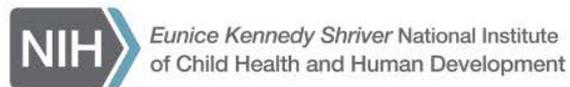
Monitoring and Oversight of Trials:

IC Perspective on Risk

Key Take Homes

- **Clinical trial monitoring and oversight expectations**

  - **Plan expected prior to award or trial start**

  - **Reporting frequency based on risk**

- **Coming soon**

  - **Guide Notice to alert community regarding expectations for monitoring and oversight**

Staff Updates

NIH Eunice Kennedy Shriver National Institute of Child Health and Human Development

Staff Transitions from NICHD Extramural

Susan Parker
GMB

Uma Reddy
PPB

New to NICHD

Jennie Conroy
GHDB

Joe Bonner
NCMRR

Bradley Cooke
SRB

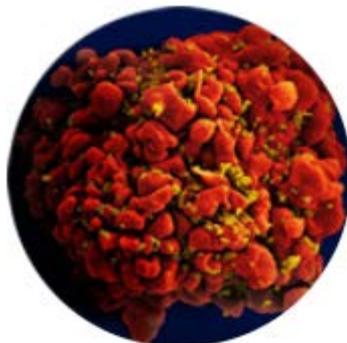Shavon Artis Dickerson
OHE

Travis Kent
FI

DER is hiring!
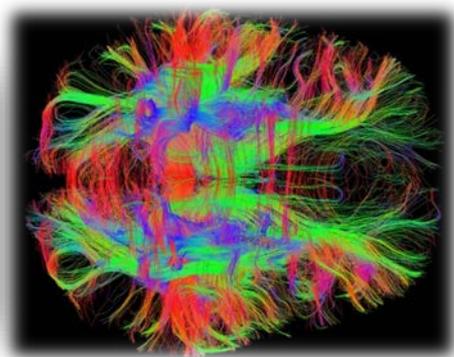

Division of Extramural Research (DER)

Funding the Best Science at NICHD…

to Advance Science & Health for All