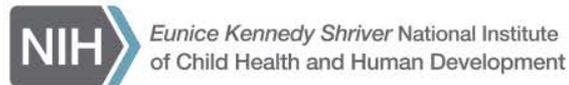


Division of Extramural Research Update

September 14, 2017

Della M. Hann, Ph.D.



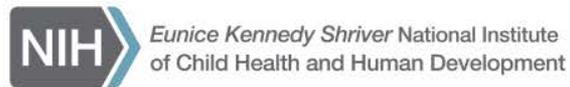


Overview

- Staff Updates
- Next Generation Researchers Initiative
 - Guide Notice and NICHD status
- Progress in Clinical Trial Reforms



Staff Updates





Tuba Fehr
IDDB

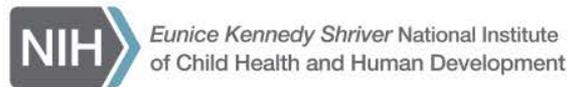


Marita Hopmann
SRB



Anne Zajicek
OPPTB

Next Generation Researchers Initiative (NGRI)





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

An **early stage investigator** or **ESI** is a Program Director / Principal Investigator (PD/PI) who has completed their terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years and who has not previously competed successfully as PD/PI for a substantial NIH independent research award.



Early-established investigators

An **early established investigator** or **EEI** is an investigator who is within 10 years of receiving their first substantial, independent competing NIH research award as an ESI and who will no longer retain their ESI status because they received a substantial award.



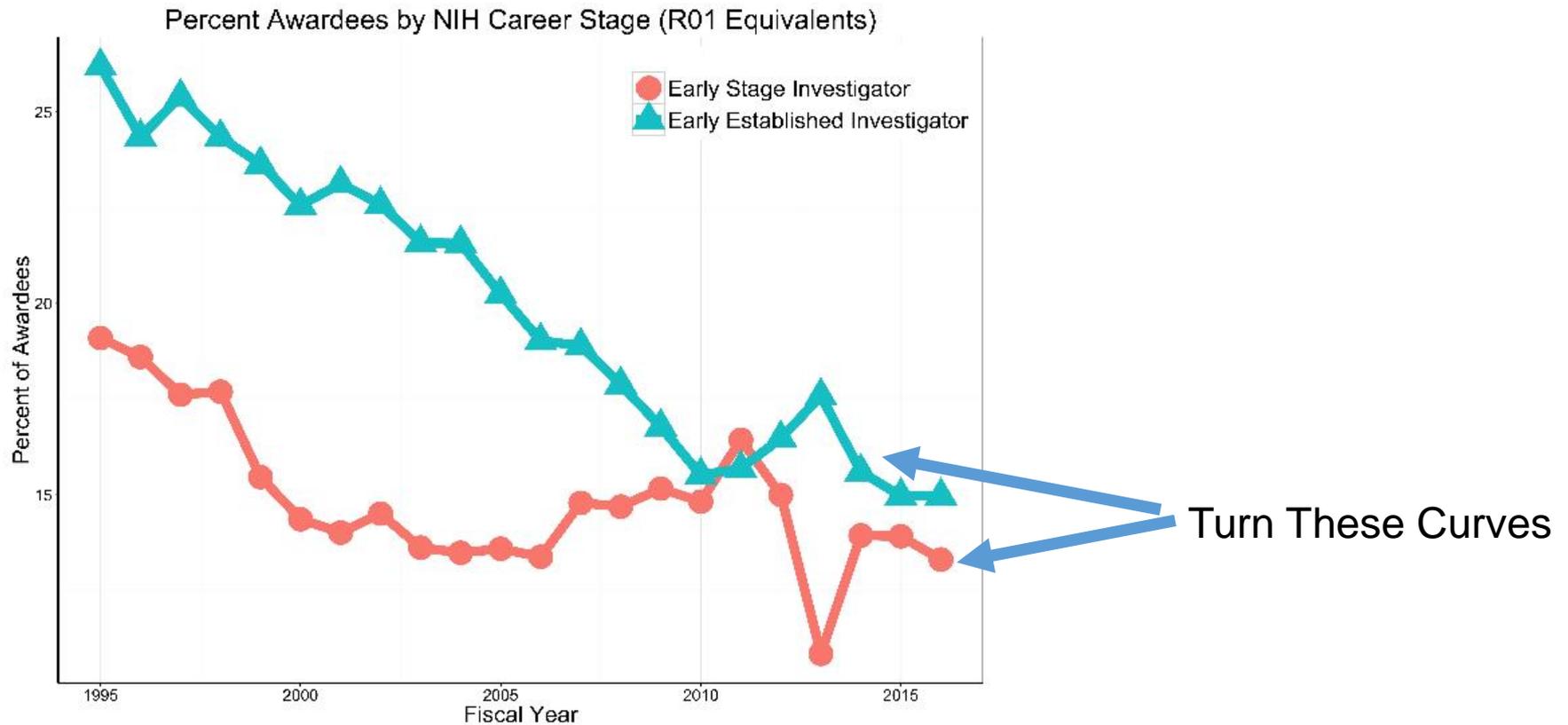
Next Generation Researchers Initiative

Policy Summary, Part I

<u>Career Status</u>	<u>Definition</u>	<u>Special Considerations</u>
Early Stage Investigator (ESI)	A Program Director / Principal Investigator (PD/PI) who has completed their terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years and who has not previously competed successfully as PD/PI for a substantial NIH independent research award.	ESI applications with meritorious scores will be prioritized for funding. The goal for FY 2017 will be to fund approximately 200 more ESI than in FY2016.
Early Established Investigator (EEI)	A Program Director / Principal Investigator (PD/PI) who is within 10 years of receiving their first substantial, independent competing NIH R01 equivalent research award as an ESI.	EEIs may be prioritized for funding of meritorious research applications if they are either: 1. losing or is at risk for losing all NIH research support if they are not funded by competing awards this year, OR 2. supported by only one active award. The goal for FY 2017 is funding 200 more EEIs across the NIH than in FY2016.

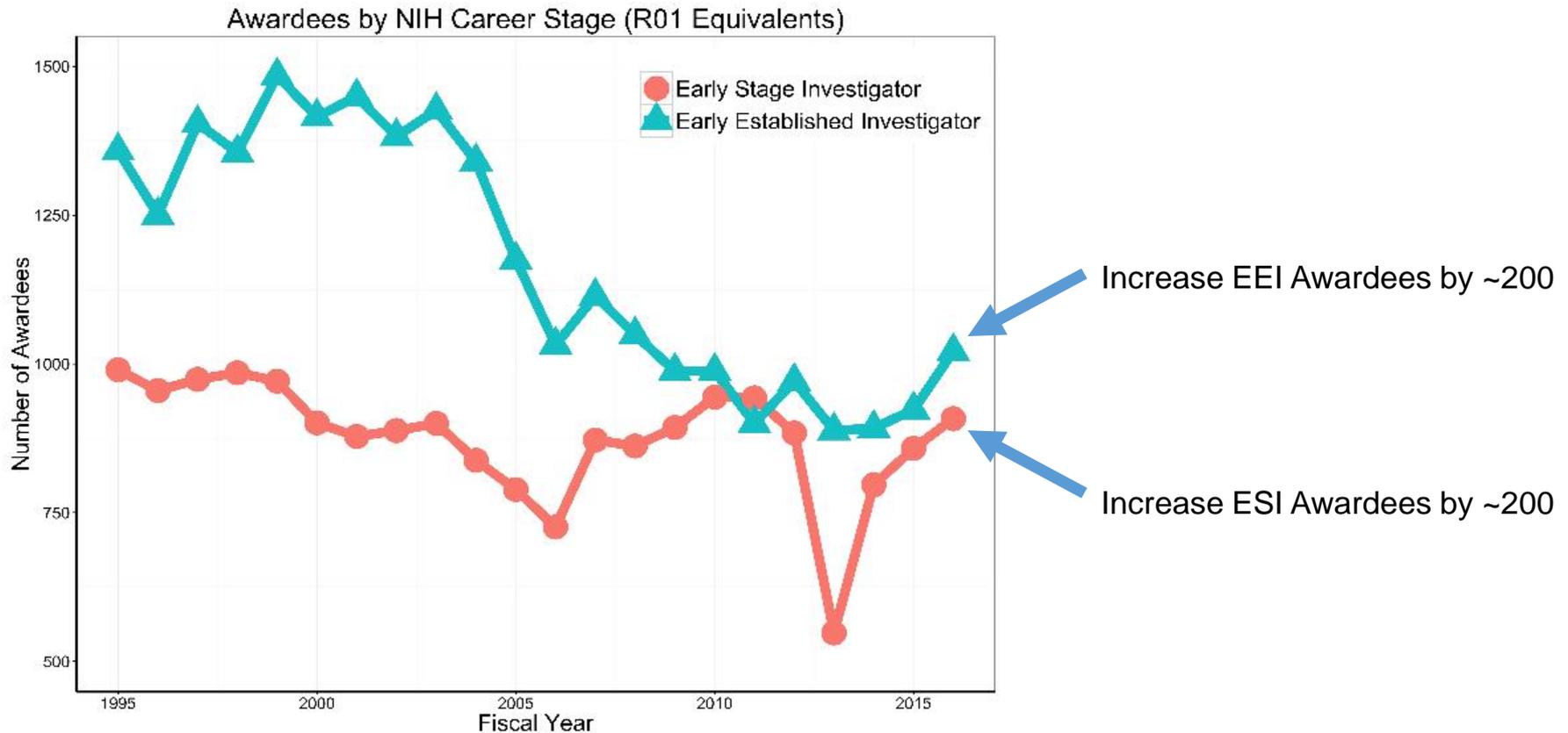


Trends among these investigators

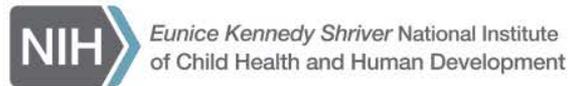




Goal of the initiative



Progress in Clinical Trial Reforms





Revised NIH Definition of Clinical Trial

A **research study** in which one or more **human subjects** are **prospectively assigned** to one or more **interventions** (which may include placebo or other control) to evaluate the effects of those interventions on **health-related biomedical or behavioral outcomes**.

[NOT-OD-15-015](#) : Effective January 25, 2015



- **Background**

- **As of January 25, 2018:**

- All applications involving one or more clinical trials must be submitted through a Funding Opportunity Announcement (FOA) or Request for Proposal (RFP) that explicitly states it will accept clinical trials
- **Reasons:**
 - Additional information requested in the application
 - Distinct changes to the review criteria



- **NICHD efforts underway**
 - Identify a “strategy” for receiving investigator-initiated applications involving clinical trials
 - Examine all existing FOAs to determine whether they accept clinical trials or not and reissuing as needed
- **Guide Notices**
 - **NICHD Policy on Receipt of Investigator-Initiated Clinical Trials (NOT-HD-17-019)**
 - **NICHD Exploratory/Developmental Research Grant (R21) will accept clinical trials (NOT-HD-17-018)**



NICHD Clinical Trial FOAs

R01

R03

R21

R15

R21

R41,42,43,44

K01

K08

K23

K99/R00

NICHD Policy on Receipt of Investigator-Initiated Clinical Trials

Notice Number: NOT-HD-17-019

Key Dates

Release Date: August 4, 2017

Related Announcements

[NOT-OD-16-147](#)

[NOT-OD-17-043](#)

[NOT-OD-17-062](#)

Issued by

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



- **OER Communications Toolkit**

- **FAQs**
- **Single IRB Policy**
- **Good Clinical Practice**

- **NICHD efforts underway**

- **Email to investigators**
- **NICHD webpage for Clinical Trials**
- **Central inbox for questions**

Clinical Trial Requirements for Grants and Contracts

NIH is launching a series of initiatives that are rolling out in 2017-2018 to enhance the accountability and transparency of clinical research. These initiatives target key points along the whole clinical trial lifecycle from concept to results reporting. Learn more about these changes and how they will affect your research.

NIH Definition of a Clinical Trial

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. [Learn more](#)



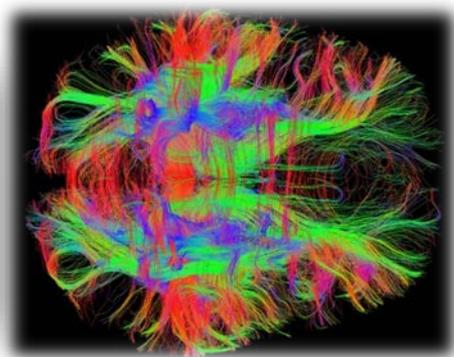
NICHD Clinical Trials Working Group



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- Rebecca Clark
- Louis De Paolo
- Sherry Dupere
- Bill Duval
- Esther Eisenberg
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- Robert Tamburro
- Katerina Tsilou
- Dennis Twombly
- Brenda Underwood
- Della White
- Ted Williams
- Karen Winer
- Margaret Young



Funding the Best Science at NICHD...



to Advance Science & Health for All

