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
New to NICHD Extramural

Tuba Fehr
IDDB
Marita Hopmann
SRB

Anne Zajicek
OPPTB
Next Generation Researchers Initiative (NGRI)
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

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<tr>
<th>Career Status</th>
<th>Definition</th>
<th>Special Considerations</th>
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<td>Early Stage Investigator (ESI)</td>
<td>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.</td>
<td>ESI applications with meritorious scores will be prioritized for funding.</td>
<td>The goal for FY 2017 will be to fund approximately 200 more ESI than in FY2016.</td>
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| 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. | EEs 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

Percent Awardees by NIH Career Stage (R01 Equivalents)

- Early Stage Investigator
- Early Established Investigator

Turn These Curves
Goal of the initiative

Increase EEI Awardees by ~200
Increase ESI Awardees by ~200
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.

• 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

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<th>FOA Codes</th>
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## 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)](https://www.nichd.nih.gov/about)
Communications Strategy

- 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
NICHD Clinical Trials Working Group

- Meredith Temple O’Connor
- Steven Berkowitz
- Bryan Clark
- Rebecca Clark
- Louis De Paolo
- Sherry Dupere
- Bill Duval
- Esther Eisenberg
- George Giacoia
- Lisa Halvorson
- Eugene Hayunga
- Deborah Henken
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- Sue Marden
- Donna Mazloomdoost
- Susan Newcomer
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- Rodney Rivera
- Denise Russo
- Samantha Sanchez
- Caroline Signore
- 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