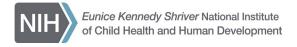
NIH Grant Mechanisms for Early Stage Investigators (ESIs)

Lisa M. Halvorson, M.D. Chief, Gynecologic Health and Disease Branch

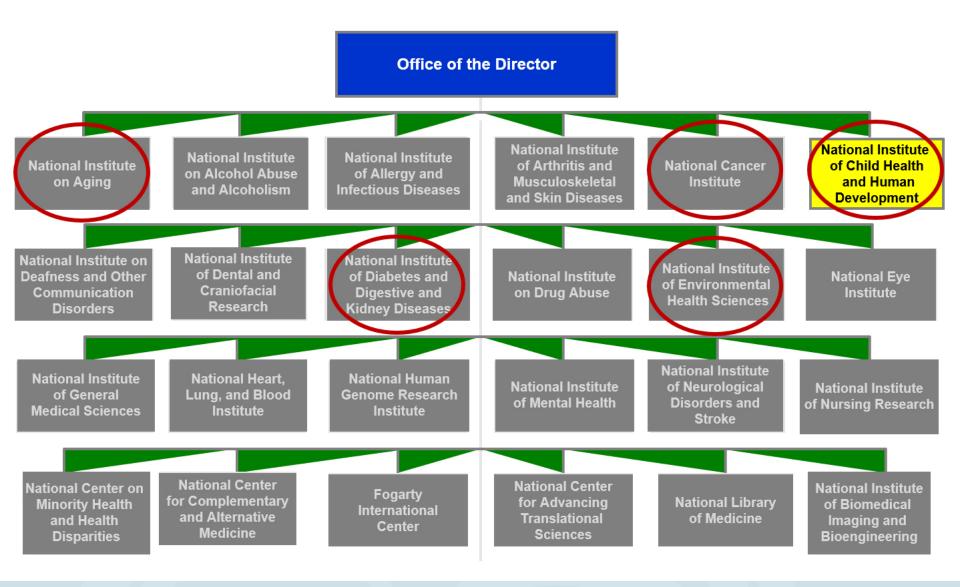


Outline

- Overview of Grant Mechanisms
- Career Development Awards ('K')
- 'R' Awards
- Loan Repayment Program
- Application Pointers



National Institutes of Health





Early Stage Investigator (ESI)/New Investigator (NI)

 A Program Director / Principal Investigator (PD/PI) who has completed their terminal research degree or end of postgraduate 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.

NICHD will include ESI investigator status as one of the program priorities when considering funding of eligible applicants.



Extension of ESI Status

- Some researchers may have lapses in their research or research training or have experienced periods of less than full-time effort.
- NIH will consider requests to extend the ESI status period for reasons that can include:
 - medical concerns
 - disability
 - family care responsibilities
 - extended periods of clinical training
 - natural disaster
 - active duty military service
- Determined on a case by case basis at the discretion of NIH

Video available at: https://www.youtube.com/watch?v=2Fr9gN7cymQ&feature=youtu.be



Overview of NIH Award Mechanisms

Pre-doctoral

Post-doctoral

Faculty

Training

- F30/F31 Individual
- T32 Institutional

Transition

- F32 Individual
- T32 Institutional
- K01 Research Scientist
- K08 Clinical Scientist
- K23 Patient Oriented
- K24 Mid-Career
- K12 Institutional

Independent

- R03 Small
- R21 Exploratory
- R01 Research
- P01 Program Project
- U Cooperative



K Awards: Common Features

Eligibility:

- US citizen or non-citizen national
- Doctoral degree
- Requires Mentor
- Cannot have had prior R01, 'P" Award

Expectation:

- 75% protected time
- 3-5 years; NICHD allows total of 6 yrs of training support
- \$100,000 salary + fringe
- \$25,000 research support
- Encouraged to apply for independent (R) funding during award



Training and Career Development NICHD Scientific Program Contact

Dennis A. Twombly, Ph.D.

Phone: 301-451-3371

Email: dtwombly@mail.nih.gov



Career Development Awards: Independent

- K01: Mentored Research Scientist Development Award
 - Research or health profession doctorate
 - NICHD: Rehabilitation Research, Child Abuse and Neglect, and Population Research
- K08: Mentored Clinical Scientist Development Award
 - Clinical doctoral degree (MD, OD, DDS, DVM, PharmD, PhD in clinical disciplines)
 - Biomedical/behavioral research including translational studies



Career Development Awards: Independent (continued)

- K23: Mentored Patient-Oriented Research Career Development Award
 - Health profession doctoral degree
 - Patient Oriented Research
- K25: Mentored Quantitative Research Career Development
 - Quantitative (e.g., statistics, economics, computer science, physics, chemistry) and engineering backgrounds
 - NIH-relevant biomedical research



K99/R00 Pathway to Independence Award

Eligibility:

- No US citizenship requirement
- No more than 4 years of postdoctoral research experience at the time of application receipt date

Expectation:

- 75% effort to research project (50% for surgical subspecialties)
- Award recipients are expected to compete successfully for independent R01 support during the R00 phase
- NICHD \$75,000 + fringe +\$25,000 research support (K99)
- R00 <\$250,000/yr

Two phases:

- 1-2 years of mentored support
- Up to 3 years of independent support contingent on an independent tenure-track research position



Institutional K Awards (K12)

- Single site awarded with investigators at multiple sites
 - RSDP
 - PSDP
 - PCCTSDP
- Multiple sites awarded
 - WRHR
 - BIRCWH
 - CHRCDA

Trainees apply directly to the program site, not to NIH



Reproductive Scientist Development Program (RSDP)

- Junior OB/GYN faculty or last year of subspecialty fellowship
- Basic/translational projects
- Two phases:
 - Phase 1 (2 years): 100% research time
 - Phase 2 (2 years): 75% research time
- \$125K salary and fringe/yr with \$25K research support/yr
- Program based at University of Missouri (Danny Schust, MD)
- Louis DePaolo, PhD depaolol@exchange.nih.gov



Women's Reproductive Health Research Program (WRHR)

- Junior OB/GYN faculty or last year of subspecialty fellowship
- 75% protected time for 2 to 5 yrs
- Basic, translational, or clinical projects in array of OB/GYN research topics
- 15 WRHR sites/30 Scholars
- Lisa Halvorson, MD lisa.Halvorson@nih.gov





Building Interdisclipinary Research Careers in Women's Health (BIRCWH)

ORWH, NICHD, NCI, NIAID, NIDCR, NIDA, IAAA, NIA, NIAMS

- Clinical PhD, MD, MD-PhD, DVM, other
- 75% protected time for 2 to 5 yrs (50% for surgical subspecialties)
- Junior faculty with plan to conduct interdisciplinary basic, translational, behavior, clinical or health services relevant to women's health (emphasis on sex differences)
 - reproductive biology
 - cancer
 - depression, addiction, adverse childhood experiences
 - neuro-immune interactions
 - HIV-related
 - cardiometabolic risk burden
 - · urinary microbiome in health & disease
- Office of Research on Women's Health Contact: Lisa Begg, DrPH, RN beggl@od.nih.gov



Pediatric Scientist Development Program (PSDP)

- Clinical fellows and junior faculty in Pediatrics
- Basic biomedical, clinical sciences, population sciences, or health services research
- 2 3 years
- 75% research time
- \$100K salary and fringe/yr with \$25K research support/yr
- Program based at Duke University
- Karen Winer, MD winerk@mail.nih.gov



Child Health Research Career Development Award (CHRCDA)

- Junior faculty within 4 years of completing subspecialty training
- Research with mentor outside of their pediatric department
- 12 sites nationally
- 2 4 years
- 75% research time
- \$100K salary and fringe/yr with \$25K research support/yr
- Andrew Bremer, MD, PhD andrew.bremer@nih.gov



Pediatric Critical Care and Trauma Scientist Development Program (PCCTSDP) Pediatric Critical Care and Trauma Scientist

- Physician-scientists (MD or DO)
- Anyone whose research interests aim at improving long-term outcomes and QoL for children who sustain critical illness or traumatic injury
- Two-phase national model
 - Phase 1: Years 1 2: Research supported by K12 Program
 - Phase 2: Years 3 5: Research supported by institution or individual K
- University of Utah
- Robert Tamburro, MD, MSc; <u>robert.tamburro@nih.gov</u>
- Tammara Jenkins, MSN, RN; tjenkins@mail.nih.gov



Development Program

(PCCTSDP)

Rehabilitation Research Career Development Programs

- General Information
 - Four national networks
 - 2-3 yrs of salary followed by another 2-3 yrs of broader support
- Physical/occupational therapists and allied health professionals
 - Comprehensive Opportunities in Rehabilitation Research Training(CORRT)
 - Rehabilitation Research and Career Development (RRCD) Program for Physical & Occupational Therapists
- Bioengineers
 - Rehabilitation Engineering Career Development Program
- Clinicians involved in Neurological Rehabilitation
 - Neurorehabilitation and Restorative Neuroscience Training Network (NRNTN)
- Ralph Nitkin, PhD <u>nitkinr@exchange.nih.gov</u>



Comparison of R03, R21, and R01

Award Mechanism	R03*	R21*	R01
Title	NIH Small Grant Program	NIH Exploratory/ Development Grant Award	Research Project Grant
Scope	Pilot or feasibility; small self- contained; secondary analysis	Exploratory; novel techniques, agents, methods or models; may require risk	Discrete, circumscribed project in are of expertise
Length	Up to 2 yrs	Up to 2 yrs	Up to 5 yrs
Allowable Costs	Up to \$50,000/yr	Not to exceed \$275,000 for entire period	Up to \$250,000/yr (unlimited)

^{*} R03/R21 not accepted by all Institutes; some have IC-specific announcements



Am I doing a Clinical Trial??

- Does your study:
 - Involve one or more human subjects?
- Wide Range

 Exploratory/ Development Pilot/ Feasibility Other Interventional Behavioral

NIH Clinical Trials

- Involve one or more interventions?
- Prospectively assign human subject(s) to intervention(s)?
- Have a health-related biomedical or behavioral outcome?
- If "yes" to ALL these questions, your study is considered a clinical trial and you MUST apply to a FOA that accepts CTs



Extramural LRP Data

Website: https://www.lrp.nih.gov

Phone: 866-849-4047

Email Inquiries: <u>Irp@nih.gov</u>

- Extramural
 - Contraception and Disability
 - Clinical
 - Clinical Disadvantaged Backgrounds
 - Health Disparities
 - Pediatric





Extramural Loan Repayment Program

- Doctoral Health Professions: MD, PhD, OD, DDS, DVM, etc.
- Citizenship: U.S. citizen, U.S national, or permanent resident
- Debt: educational debt > 20 percent of salary
- 1st year: amount awarded is equal to one-fourth of the total eligible debt up to \$50,000
- Perform research > 20 hrs/week
- Renewal for 1-2 years
- Research not prohibited by federal law or NIH/HHS policy
- Deadline: September 1 Nov 15, 2019 (future dates not yet released)
- Dr. Steve Kaufman kaufmans@mail.nih.gov



Pointers for submitting any application?

- Start the writing process early
- Be sure you are applying to the right LRP/award mechanism
- Know the funding priorities of the NIH Institute that will review your application
- Form an advisory team: include your mentor(s) and other trusted investigators who know your field
- Talk to your Program Officer/LRP Liaison specific aims
- Identify people for strong letters of recommendation/support
- Contact your lender for loan information (LRP)
- Submit the application before deadline to allow time to correct any errors in grants.gov



NIH Regional Seminars

- Fundamentals of the NIH
- Compliance
- Peer Review
- Grant Writing for Success
- Pre-Award and Post-Award Issues
- Animal and Human Subject Research
- Electronic Interactions with NIH
- New Investigators' Track: Mapping your Career

- Meeting Schedule
 - https://grants.nih.go
 v/news/contact-in person/seminars.ht
 m#upcoming
- Presentation Archive
 - https://regionalsemi nars.od.nih.gov/pho enix2019/presentati ons/



Questions?

Lisa Halvorson, MD Chief, GHDB

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• Email: lisa.halvorson@nih.gov



