

# NIH Virtual Seminar November 1- 4, 2021

## Understanding NIH Career Development “K” Awards

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## What are Career Development “K” awards?

**Purpose:** Awards to provide scholars with protected time to conduct research and career development activities leading to independence in the biomedical, behavioral, or clinical sciences.

**Types of Awards:** There are multiple “K” Award types designed for different scientific/educational backgrounds and career stages.

- **Mentored** – For early-stage investigators needing mentored research training
- **Non-mentored** – For independent investigators to acquire new research skills or to support mentoring activities
- **Institutional** – Awards to institutions to support multiple K-level scholars

# Research Training and Career Development

## Fellowships & Career Awards

### Research Grants

R03 Small Grant

R21 Exploratory  
Developmental  
Grant

R01 Research  
Project Grant



T32 Institutional Training Grants (Predoctoral slots)  
F30 Pre-doctoral Fellowships (MD/PhD Programs)  
F31 Pre-doctoral Fellowships (Parent F31)  
F31 Diversity Pre-doctoral Fellowships

T32 Institutional Training Grant (Post-doctoral slots)  
F32 Individual Post-doctoral Fellowships

K22 Career Transition Award (some ICs)  
K99-R00 Pathway to Independence Award

K12 Institutional Career Development Award

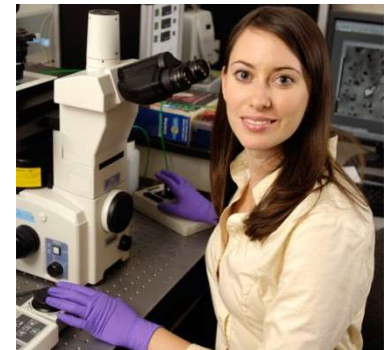
K01 Mentored Research Scientist Development Award  
K08 Mentored Clinical Scientist Development Award  
K23 Mentored Patient-Oriented K Award  
K25 Mentored Quantitative K Award

K02 Independent Scientist Award  
K24 Mid-career Award in Patient-Oriented Research



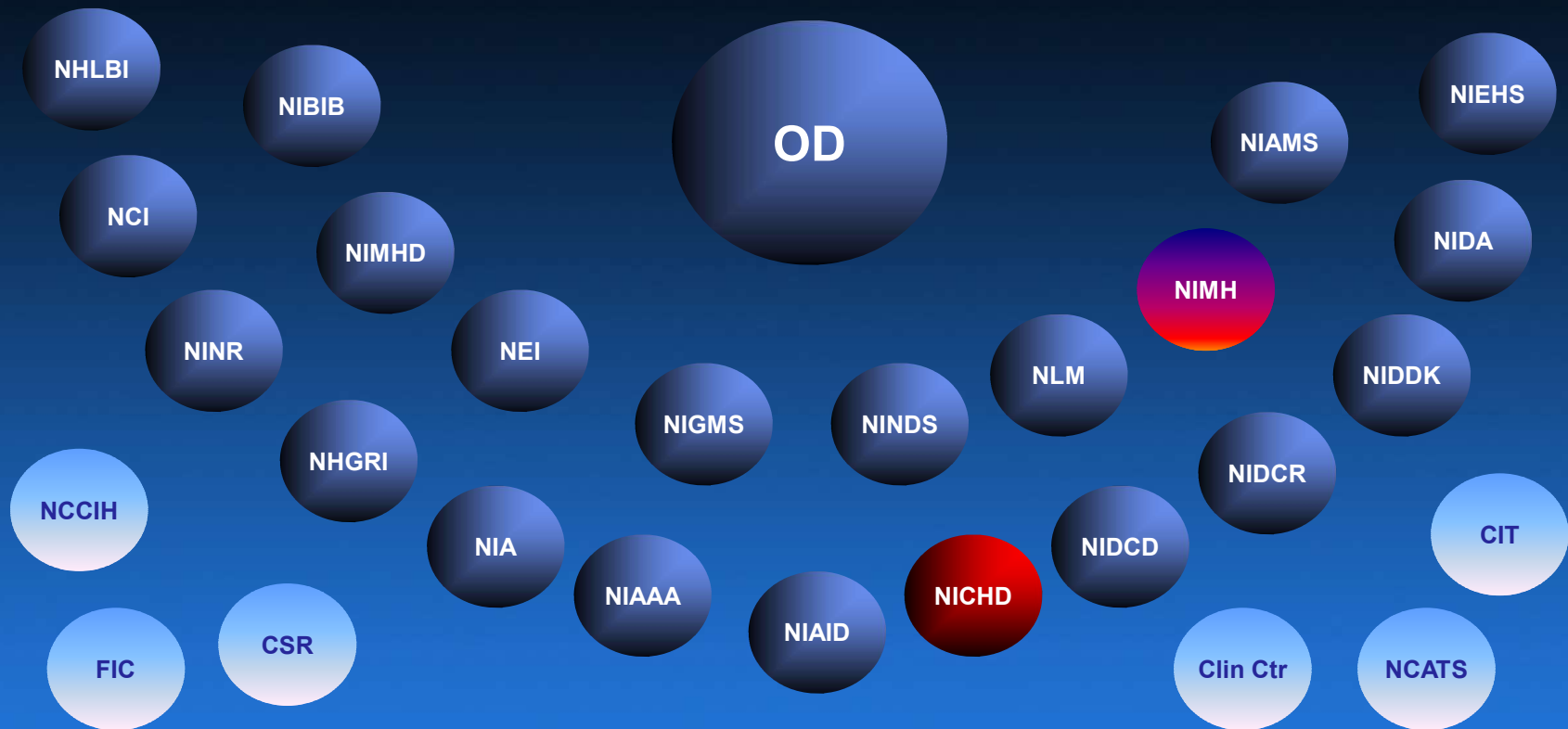
## Mentored K award programs

- K01** Mentored Research Scientist Development Award (usually PhDs)
- K07** Academic Career Development Award
- K08** Mentored Clinical Scientist Development Award (clinical degrees)
- K18** Research Career Enhancement Award for Established Investigators
- K22** Research Career Award for Transition to Independence (not NICHD)
- K23** Mentored Patient-Oriented Research Development Award (clinical degrees)
- K25** Mentored Quantitative Research Development Award
- K43** Emerging Global Leader Award
- K99/R00** NIH Pathway to Independence Award



# NIH Organization

*Different NIH institutes have different K programs and requirements*



# Refer to Program Announcements (PAs) !!

## Funding Opportunity Title

NIH Pathway to Independence Award (**Parent K99/R00 - Independent Clinical Trial Not Allowed**)

## Funding Opportunity Announcement (FOA) Number

PA-18-398 (Clin Trial not allowed); PA-18-397 (Clin Trial Req'd)

## Components of Participating Organizations (all NIH ICs, e.g.)

National Cancer Institute (NCI)

National Institute on Aging (NIA)

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

*Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHHD)

National Institute on Deafness and Other Communication Disorders (NIDCD)

**Special Note:** Not all NIH Institutes and Centers participate in Parent Announcements. Applicants should carefully note which ICs participate in this announcement and view their respective areas of research interest and requirements at [Table of IC-Specific Information, Requirements and Staff Contacts](#) website. ICs that do not participate in this announcement will not consider applications for funding. Consultation with NIH staff before submitting an application is strongly encouraged.

# K99 Table of IC-specific Information



HOME	ABOUT GRANTS	FUNDING	POLICY & COMPLIANCE	NEWS & EVENTS	ABOUT OER
		<p><b>Salary Support:</b> Up to \$50,000 plus fringe benefits per year.  <b>Research Support:</b> Up to \$20,000 per year.</p>			
<p><b>Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)</b></p> <p><b>Scientific Program Contact:</b>                      Dennis A. Twombly, Ph.D.                      Phone: 301-451-3371                      Email: <a href="mailto:dtwombly@mail.nih.gov">dtwombly@mail.nih.gov</a></p> <p><b>Grants Management Contact:</b>                      Ryan Talesnik                      Phone: (301) 435-6976                      Email: <a href="mailto:talesnikr@mail.nih.gov">talesnikr@mail.nih.gov</a></p>		<p><b>NICHD Specific Information:</b>                      NICHD offers research career development awards in areas relevant to normal and abnormal human development, including contraception, fertilization, pregnancy, childbirth, prenatal and postnatal development, and childhood development through adolescence. The mission areas also include research on intellectual and developmental disabilities and rehabilitation medicine. More detailed information can be found at: <a href="http://www.nichd.nih.gov/research/by-nichd/pages/index.aspx">http://www.nichd.nih.gov/research/by-nichd/pages/index.aspx</a>.                      The K99/R00 program is designed for postdoctoral fellows (PhDs, MDs, or other) whose formal research training is nearly complete, and who expect to find a tenure-track or equivalent faculty position within 2 years of receiving the award. Those whose career development would benefit from further research training should also consider the mentored Career Development Awards offered by NICHD (e.g., K01, K08, K23, K25). Prospective applicants are strongly encouraged to email or call the NICHD Scientific/Research Contact to help choose among these career development award mechanisms, to determine K99/R00 eligibility, and to assess relevance of the proposed project to the NICHD mission.                      Awardees must spend at least one year on the K99 phase of the award.</p> <p><b>Salary Support:</b> For the K99 phase of the award, NICHD provides salary of up to \$75,000 plus fringe benefits per year.  <b>Research Support:</b> Up to \$25,000 per year.</p>			
<p><b>National Institute on Deafness and Other Communication Disorders (NIDCD)</b></p> <p><b>Scientific Program Contact:</b></p>		<p><b>NIDCD Specific Information:</b>                      NIDCD uses the K99/R00 program to support outstanding senior postdoctoral investigators in NIDCD research areas that are ready to complete their transition to become an independent investigator.</p> <ul style="list-style-type: none"> <li>Application must demonstrate its contribution to NIDCD and its fit to NIDCD's Mission, Research Priorities, and Strategic Plan.</li> </ul>			

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# Mentored Career Development (K) Awards



<b><u>Purpose:</u></b>	<b>Develop new research skills, release time for research and training activities in the biomedical, behavioral, or clinical sciences</b>
<b><u>Eligibility:</u></b>	<b>Doctoral degree (PhD, MD, MD/PhD, DDS, DVM, etc.) US Citizens or permanent residents (except K99) Typically junior faculty level applicants (except K99) Current/prior PD/PI on K awards or major research project grants are ineligible for mentored K awards</b>
<b><u>Duration:</u></b>	<b>3 - 5 years (not renewable)</b>
<b><u>Commitment:</u></b>	<b>Full-time appointment, minimum 75% effort</b>
<b><u>Support:</u></b>	<b>Salary \$75,000 - \$100,000 + fringe (typical; IC dependent)</b>
<b><u>Research support:</u></b>	<b>\$25,000 to \$50,000 (see IC Tables)</b>





## Pathway to Independence Award (K99/R00)

- **Purpose:** *2-phase award to help new researchers secure a tenure-track position and launch an independent research career.*
- **Phase I: K99 Mentored Phase (1-2 years – tight window)**
  - Supports late-stage **postdoctoral** research training
  - Provides salary + limited research expenses (varies, see IC Tables)
  - For Intramural fellows, **DIR pays salary and expenses**
- **Phase II: R00 Independent Phase (typically 3 years)**
  - Requires tenure track or equivalent **faculty position**
  - Launch independent research program
  - \$249,000 **total costs** per year (direct costs + full indirect costs)



## K99/R00 eligibility

- **Basic or clinical doctoral degree (ie, postdoctoral fellow or equivalent)**
- **Domestic extramural or intramural institutions**
- **US citizens or non-citizens**
- **No more than 4 years postdoctoral research experience (-01 or -A1)**
  - **Exceptions for family / medical leave, military service, unemployment, clinical time**
- **Cannot have held independent faculty-level position**
- **Cannot have been independent Principal Investigator on:**
  - **Mentored Career Development Awards (eg, K01, K08, K23, K25)**
  - **Research project grants (eg, R01, R03, R21)**
  - **Other peer-reviewed NIH or non-NIH grants >\$100,000 /yr direct costs**
  - **Project leaders on sub-projects of Program Project (P01) or Center (P50)**



## **Non-mentored K awards (Independent)**

K02, K05, K24



- Not all NIH Institutes Participate: Refer to FOA!
- Candidates must have active, independent peer-reviewed grant support at the time of award, usually from funding IC.
- Awards support research career development or mentoring (K24)
- Effort Requirements: IC-specific (check FOA)
- NIH Salary Cap Applies
- Renewable at some ICs only



## Institutional K Programs (K12, KL2)

- **Purpose:** Awards to institutions to provide mentored research training for groups of clinical fellows and scientists to help them become independent research investigators.
- **Models:** Nationwide programs versus local-institutional programs
- **Scholar eligibility:** Final year of fellowship through early faculty
- **Commitment:** Minimum 75% effort on the K12; usually 25% clinical effort
- **Duration of support:** 2 - 5 years (6 - 8 yrs overall K support at some ICs)
- **Allowable costs:** Varies with IC (see FOA)

# How to apply for a K award



The screenshot shows the NIH Grants website with a navigation menu and a list of filtered application instructions. The navigation menu includes: HOME, ABOUT GRANTS (highlighted), FUNDING, POLICY & COMPLIANCE, NEWS & EVENTS, and ABOUT OER. The main content area is titled "Filtered Application Instructions" and contains a table with the following rows:

Letter	Instruction Type	Description	Link
R	Research Instructions	Guidance for research only	PDF
K	Career Development Instructions	Guidance for career development only	PDF
T	Training Instructions	Guidance for training only	PDF
F	Fellowship Instructions	Guidance for fellowship only	PDF
M	Multi-Project Instructions	Guidance for multi-project only	PDF
B	SBIR/STTR Instructions	Guidance for small business only	PDF

At the bottom of the page, there is a "Back to Top" button.

Follow SF424 instructions

Individual K awards



Institutional K awards



# Clinical Trials Requirements



**Identifying Whether NIH Considers Your Study to be a Clinical Trial is Crucial !**

**It impacts whether you need to:**

- ✓ Respond to a **clinical trial-specific FOA**
- ✓ Address additional **review criteria** specific for clinical trials
- ✓ **Register and report** your clinical trial in ClinicalTrials.gov

<https://grants.nih.gov/policy/clinical-trials.htm>

[Or Google “NIH Clinical Trials”]

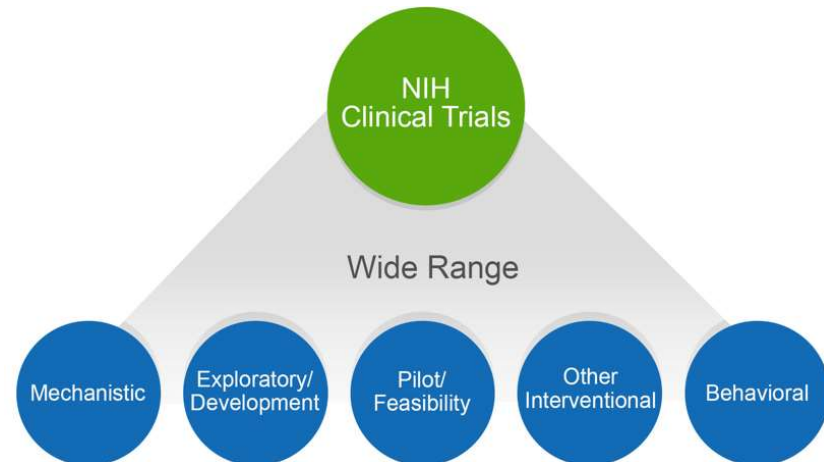
<https://grants.nih.gov/policy/clinical-trials.htm>  
[Or Google “NIH Clinical Trials”]

## NIH Might Consider Your Human Subjects Research to be a “Clinical Trial”

### Does your study...

- ✓ Involve one or more **human subjects**?
- ✓ **Prospectively assign** human subject(s) to intervention(s)?
- ✓ Evaluate the **effect of intervention(s)** on the human subject(s)?
- ✓ Have a **health-related biomedical or behavioral outcome**?

If “yes” to ALL of these questions, your study is considered a clinical trial



Unsure how to answer the questions? We have a tool that can help! <https://grants.nih.gov/ct-decision/>



# K Application Content



- **Candidate Section**
  - Candidate's Background
  - Career Goals and Objectives
  - Plan for Career Development Activities During Award Period
- **Research Plan**
  - Research Strategy (Significance, Innovation, Approach) – Indicate research planned for K99 and R00 phases
- **Plans and Statements of Mentor, Co-Mentor(s) – 6 pages combined**
- **Letters of Support from Collaborators, Contributors, Consultants – 6 pages combined**
- **Environment & Institutional Commitment to the Candidate**
- **Training in the Responsible Conduct of Research**
- **Appendix (Warning: Very few materials are allowable!)**
- **Reference Letters: for Mentored Ks -- Separate from Application**

# K Awards: SCIENTIFIC Review



## ❖ Overall Impact Score (not a numerical average)

### Scored Review Criteria (Scale 1-5)

- Candidate
- Career Development Plan
- Research Plan (Rigor and reproducibility, SABV)
- Mentor(s), Consultant(s), and Collaborator(s)
- Environment and Institutional Commitment to the Candidate

### Additional Review Criteria

- Protection for Human Subjects
- Inclusion of Women, Minorities, and Children
- Vertebrate Animals
- Biohazards
- Resubmission, Renewal, Revision factors
- Study Timeline (for Clinical Trials)

### Additional Review Considerations

- Training in the Responsible Conduct of Research
- Select Agents Research
- Resource Sharing Plans
- Budget & Period of Support



# Time Line: Application to Award



- Receipt Dates: *Feb/June/October 12* New K Applications
  - Review: 4-6 months later
  - Council: 3-4 months
  - Award: 1-2 months
  - Total time until award:  
9-10 months
- 
- Total time for New + Resubmission:  
12-18 months

***Plan with your Mentor and Department Chair!***



## R01 Funding for New Investigators and Early Stage Investigators (ESI)

- **“New Investigator”**: Applicant who has not previously competed successfully as PD/PI for a significant NIH independent research award (i.e., R01 grant)
- **“Early Stage Investigator”**: A New Investigator who is within 10 years of the terminal doctoral degree or end of formal clinical training (residency and fellowship)
- NIH funds R01s of ESIs at ***more favorable pay lines*** !!
- Pay lines and relative advantage differ by NIH Institute; 3%-10% more generous pay lines
- Advice for Early Stage Investigators
  - Apply for R01 now !!!!! (*If you have preliminary data*)



You have a fundable score, now what?



# Pre-Award Review



## **Just-in-Time (JIT):**

- Other Support (PI)
- IRB/IACUC Approval(s)
- Human Subjects Protection Education
- PI Salary (Current salary and fringe if below the cap)

**Institutional Commitment:** Ensure “protected time”

## **Clinical Trials:**

Milestones coordinated between PI and PO

Internal risk assessment determination (NICHD)

# Post Award Reporting



## Research Performance Progress Report (RPPR)

- Due 45 days prior to the next budget period start date (except K12, KL2)
- Streamlined Non-Competing Award Process (SNAP) (except K12, KL2)
- Publication List
- Responsible Conduct of Research
- Mentor Report(s)
- Key Personnel (PI) Effort Changes
- Mentor Changes
- Other Support Changes
- Large Unobligated Balance Justification



# Post-Award Actions (No Prior Approval)



1. First No-Cost Extension up to 12 months (except K99s)
2. Rebudgeting (within scope)
3. Equipment Purchase (within scope)
4. Carryover (except Institutional K Awards)
5. Temporary Off-Site Training Experiences (< 3 months)
6. Leave of Absence (< 3 months)

## Post-Award Actions (Prior Approval Required)



1. Change of Institution
2. Change of Mentor
3. Unpaid leave (up to 12 months)
4. Leave (> 3 months)
5. Temporary off-site training experiences (> 3 months)
6. Temporary effort reductions
7. Additional NCE requests and all K99 extension requests
8. Early scholar termination on Institutional K awards

# Temporary Effort Adjustments

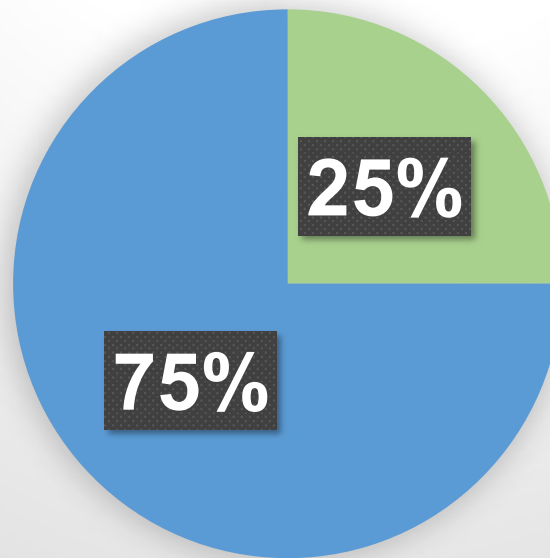


- PI may temporarily reduce their effort down to 50% for up to 12 continuous months during the project period
- Allowed for personal/family situations such as parental leave, childcare, elder care, medical conditions, or a disability
- Permission to temporarily reduce effort will not be approved to accommodate job opportunities, clinical practice, clinical training, or joint appointments
- See **NOT-OD-18-156** and **NIHGPS Section 12.3.6.4**

# K Award Salary Provisions



Minimum K effort:  
Salary supplementation  
from non-Federal  
sources only

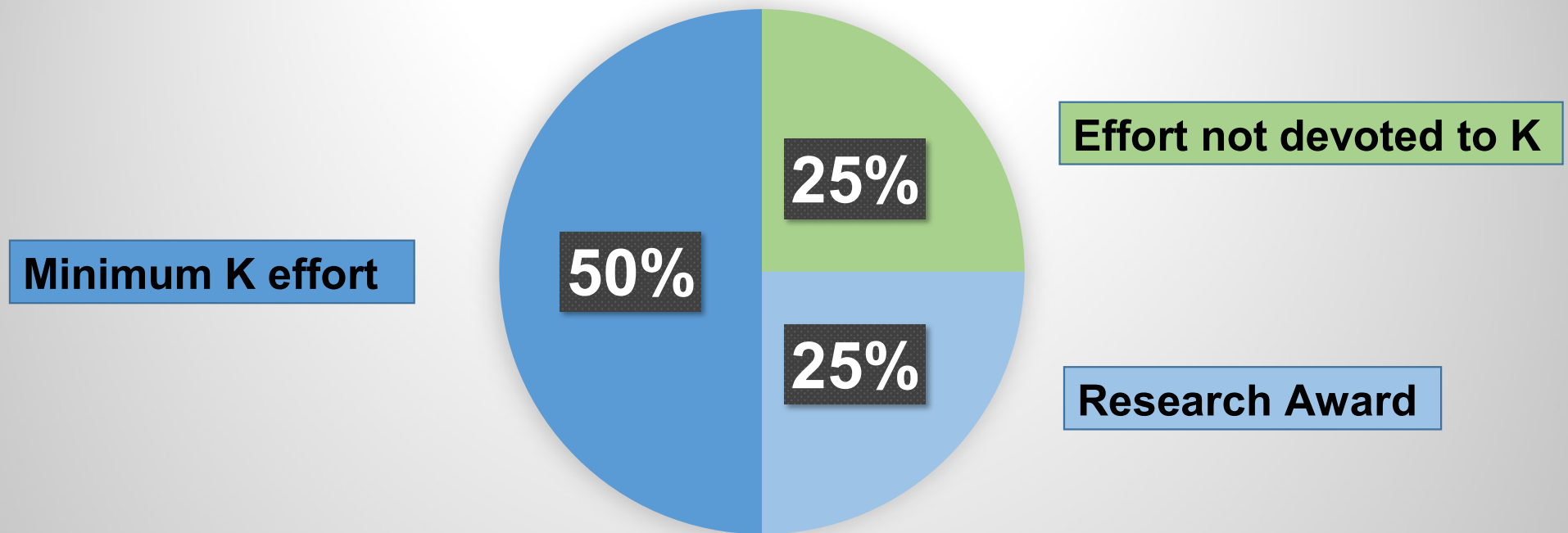


Effort not devoted to K:  
Salary compensation from  
Federal or non-Federal  
source

Salary Supplementation and Compensation on 3-5 Year Mentored K Award

See **NOT-OD-17-094** and **NIHGPS Section 12.8.1**

# Concurrent Support on Mentored K Award



Effort reduction in final two years of a 3 to 5-year individual mentored K award allowed when the PI successfully competes as a PI/PD on a Federal research award or grant of \$100K direct costs from non-Federal sources

See **NOT-OD-18-157** and **NIHGPS Section 12.3.6.2**

# K99-R00: Transition to R00 Phase



- No less than one year on K99 phase, no more than 2 years
- Request transition at least 2 months prior to faculty offer/appointment (materials listed in FOA)
- Administrative Review by NICHD Transition Committee
  - Considerations:
    - Type of faculty appointment (Tenure track or equivalent)
    - Academic environment (faculty, resources, students, reputation)
    - Progress on K99 research and career development objectives
    - Start-up package (space, equipment, supplies, staff, etc)
    - Minimum total research effort = 75% (institutional assurance)
- Budget: \$249,000 TC per year (negotiated with institution)
- Consult with Program Staff!! (6 mo before and during transition)



## Final Reporting

FRPPR - Final Research Performance Progress Report (except K99, K22)

Federal Financial Report (FFR) (annual FFR required on Institution K)

- Due within 120 days after the project period end date.
- Grantees should ensure final expenditure report and final cash reports align
- Project Outcomes should be written for lay public

Final Invention Statement (except Institutional K awards)



# RESOURCES



NIH's Research Career Development homepage (description of programs, FAQs, Policy Notices, NIH Resources)

<https://researchtraining.nih.gov/programs/career-development>

Applying Electronically:

<http://grants.nih.gov/grants/how-to-apply-application-guide.htm>

Career Development Chapter of NIH Grants Policy Statement:

[http://grants.nih.gov/grants/policy/nihgps/HTML5/section\\_12/12\\_research\\_career\\_development\\_k\\_awards.htm?Highlight=career development](http://grants.nih.gov/grants/policy/nihgps/HTML5/section_12/12_research_career_development_k_awards.htm?Highlight=career%20development)

# RESOURCES



Current K Award Funding Mechanisms Available:

<https://researchtraining.nih.gov/programs/career-development>

FAQs for all things K (also a mix of other training FAQs):

<http://researchtraining.nih.gov/resources/faq>

Career Path Resource:

<https://researchtraining.nih.gov/career-path>

## Applicant: Sources of Guidance



- NIH Program Announcements (PAs, RFAs)
    - Purpose, eligibility, allowable costs, review criteria
    - Tables of IC-specific Information, Requirements, & Staff Contacts
  - [www.nih.gov](http://www.nih.gov) (follow links to “training” or “peer review”)
    - Office of Extramural Research (“OER” grant programs, forms)
    - Center for Scientific Review: [www.csr.nih.gov](http://www.csr.nih.gov) (review process)
    - Institute web sites: [www.nichd.nih.gov](http://www.nichd.nih.gov) (program interests)
  - Mentor (current and/or proposed)
  - Department Chair or Administrator
  - Institution’s Sponsored Programs Office
  - Other colleagues & faculty
- **Contact NIH Program Staff (before applying and after review) !!**



# Contacts

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**For other Questions about this presentation, go to:**

- **NICHD Booth**
- **Ask a Training Officer Booth**