Writing a NIH Career Development Award: Lessons Learned

Hoda S. Abdel Magid, MHS, PhD

October 3, 2022

Lessons

1. Talk to (many) successful applicants
2. Read (many) successful applications and resubmissions
3. Identify the right funding mechanism for you
4. Understand the application components and review criteria
5. Pick the right institute
6. Talk to your PO
7. Apply as early as possible
8. Give yourself plenty of time

Personal Disclaimers

1. I was only recently awarded the K99/R00
2. These experiences are my own personal experiences – everyone's experiences are different.
3. I could not have done *any* of this without the support of a village including the Stanford Grant Writing Academy!

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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

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Mentored K Awards

- 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
- *+ the diversity versions of these grants (if available)*

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K Awards

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

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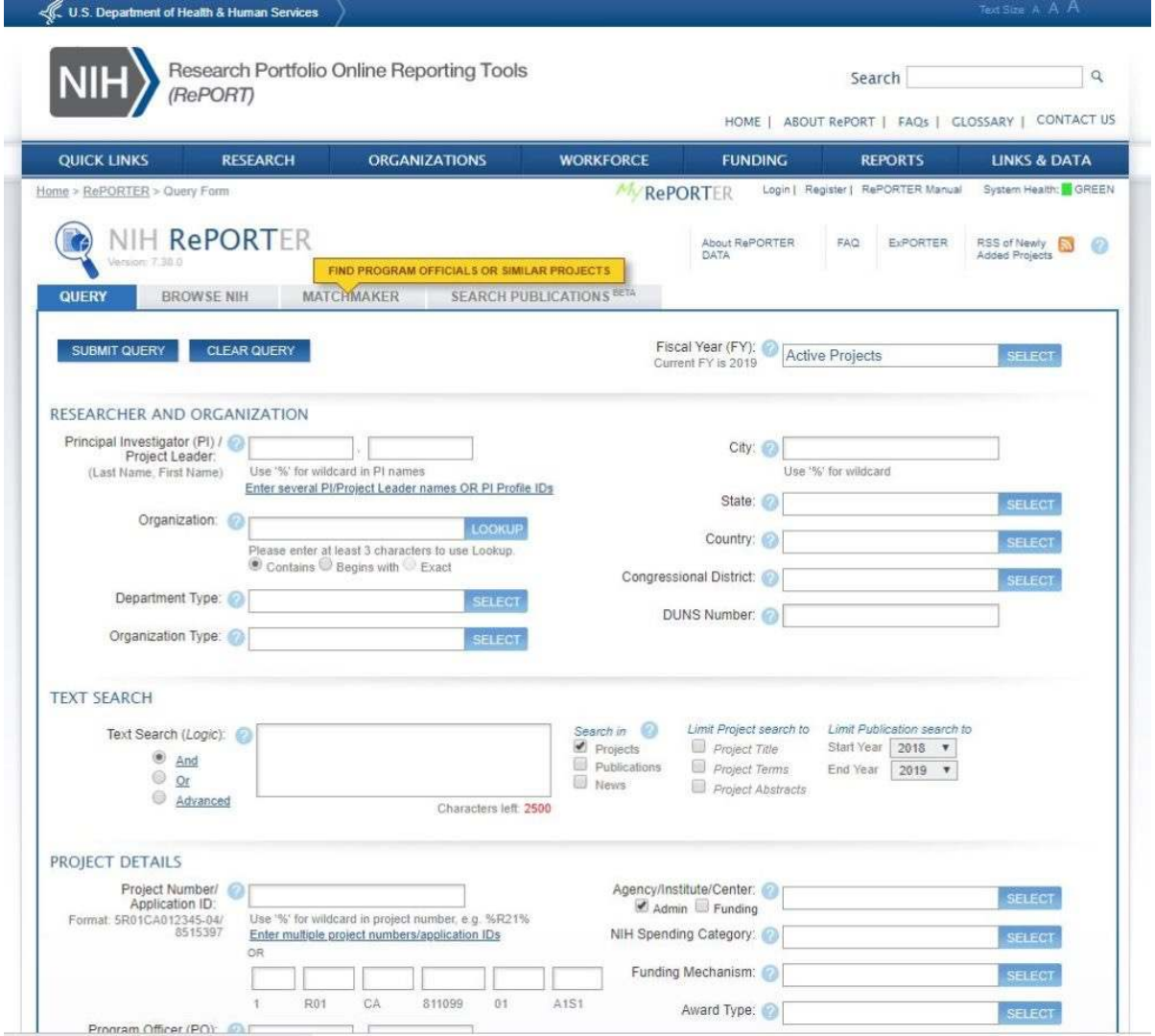
Lesson 1:

Talk to (many) successful applicants.


U.S. Department of Health & Human Services
Text Size A A A
NIH Research Portfolio Online Reporting Tools (RePORT)
Search
HOME | ABOUT RePORT | FAQs | GLOSSARY | CONTACT US
QUICK LINKS
RESEARCH
ORGANIZATIONS
WORKFORCE
FUNDING
REPORTS
LINKS & DATA
Home > RePORTER > Query Form
MyRePORTER
Login | Register | RePORTER Manual
System Health: GREEN
NIH RePORTER
Version: 7.38.0
About RePORTER DATA
FAQ
ExPORTER
RSS of Newly Added Projects
FIND PROGRAM OFFICIALS OR SIMILAR PROJECTS
QUERY
BROWSE NIH
MATCHMAKER
SEARCH PUBLICATIONS BETA
SUBMIT QUERY
CLEAR QUERY
Fiscal Year (FY):
Current FY is 2019
Active Projects
SELECT
RESEARCHER AND ORGANIZATION
Principal Investigator (PI) / Project Leader:
(Last Name, First Name)
Use '%' for wildcard in PI names
Enter several PI/Project Leader names OR PI Profile IDs
Organization:
LOOKUP
Please enter at least 3 characters to use Lookup.
Contains Begins with Exact
Department Type:
SELECT
Organization Type:
SELECT
City:
Use '%' for wildcard
State:
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Country:
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Congressional District:
SELECT
DUNS Number:
TEXT SEARCH
Text Search (Logic):
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Advanced
Characters left: 2500
Search in
Projects
Publications
News
Limit Project search to
Project Title
Project Terms
Project Abstracts
Limit Publication search to
Start Year 2018
End Year 2019
PROJECT DETAILS
Project Number/ Application ID:
Format: 5R01CA012345-04/ 8515397
Use '%' for wildcard in project number, e.g. %R21%
Enter multiple project numbers/application IDs
OR
1 R01 CA 811099 01 A1S1
Agency/Institute/Center:
Admin Funding
SELECT
NIH Spending Category:
SELECT
Funding Mechanism:
SELECT
Award Type:
SELECT
Program Officer (PO):

Lesson 2:

Read (many) successful applications and resubmissions.

Specific Aims Examples

Proposed research is important

Goal is appropriate for PI / team

Aims address specific questions

Return on investment is expected

Contact PD/PI: Putnam, Nicole E

SPECIFIC AIMS

The impact of innate immune recognition of *Staphylococcus aureus* on bone homeostasis and skeletal immunity

Bone is constantly remodeled through the coordinated efforts of bone-forming osteoblasts (OBs) an one-resorbing osteoclasts (OCs). This process is referred to as bone homeostasis and is tightly regulated b ocal and systemic factors, including cytokines, hormones, and growth factors. *Staphylococcus aureus* is th eading cause of invasive bone infection (osteomyelitis), during which inflammation leads to altered interaction etween skeletal cells. Dysregulation in bone homeostasis triggers aberrant bone formation and bon estruction, which may result from changes in skeletal cell physiology during osteomyelitis that are distinc rom cell death. Our preliminary data show that bacterial components modulate the differentiation of OC steoclastogenesis) from myeloid cells with and without the canonical OC differentiation factor, recepto ctivator of nuclear factor κB-ligand (RANKL). Specifically, BM treatment with *S. aureus* supernatants induce OC differentiation without canonical RANKL signaling, and limits OC formation when pretreated with RANKL The primary objective of this proposal is to define the mechanisms by which bacterial pathogens alte steoclastogenesis to impact bone homeostasis and skeletal immunity.

Skeletal cells are known to express innate pattern recognition receptors (PRRs), but the contribution o nnate sensing by OC PRRs, such as Toll-like receptors (TLRs) towards pathogen clearance and bon emodeling during *S. aureus* osteomyelitis has not yet been explored. In order to further define the contributio f skeletal cell PRRs to altered bone homeostasis and antibacterial immunity during osteomyelitis, we focuse n the critical PRR signaling adaptor MyD88, which is required for TLR and IL-1 family cytokine signaling. I reliminary studies, data support a MyD88-mediated mechanism by which bacteria perturb OC differentiation mphasizing the importance of innate signaling in modulating osteoclastogenesis. Overall, I hypothesize the *S. aureus* modulates OC precursor (pre-OC) cell biology and bone remodeling through ligation of OC PRR nd the induction of inflammation. To test this hypothesis, we propose two integrated Aims that will define how *S. aureus* perturbs the differentiation and functional ability of OC-like cells to resorb bone, and determine hov nnate activation of skeletal cells affects bacterial clearance and bone homeostasis in a powerful nev steomyelitis murine model that is capable of precise quantification of pathogen-induced changes in bon urnover. The Aims will elucidate bacterial-induced mechanisms of altered bone remodeling and further defin he ability of skeletal cells to respond to *S. aureus*. These studies have the potential to significantly impac uman health by identifying therapeutic targets to limit bone destruction during osteomyelitis. The Aims are:

Aim 1: Define the role of TLRs and IL-1R in *S. aureus*-mediated perturbation of osteoclastogenesis.

Based on preliminary studies that suggest a MyD88-mediated mechanism of OC perturbation by bacteria omponents *in vitro*, I hypothesize that *S. aureus* modulates pre-OC cell biology through TLR recognition or IL R signaling upstream of MyD88. To test this hypothesis, we will perform osteoclastogenesis assays on bone arrow (BM) cultures from wild-type and immune-deficient mouse strains, including TLR2, TLR9, and IL-1R eficient mice, with and without RANKL stimulation, components of *S. aureus*, TLR agonists, or recombinan L-1 to (i) identify changes in expression of TLRs and factors known to modulate osteoclastogenesis, (ii) defin he activation status of intracellular signaling cascades and transcription factors, and (iii) investigate the unctionality of OCs induced by bacterial components with bone resorption assays. Taken together, these data ill detail how bacterial stimulation modulates OC differentiation and function through TLR and IL-1 signaling.

Aim 2: Elucidate the role of skeletal cell-specific MyD88 signaling on pathogen clearance and bone emodeling during *S. aureus* osteomyelitis.

Aim 1 will identify *in vitro* changes caused by *S. aureus* during osteoclast differentiation, including lterations in OC signaling and function. Our *in vitro* assays demonstrate that MyD88 in skeletal cell precursors ould be responsible for downstream changes following *S. aureus* stimulation. Interestingly, preliminary data btained in our *S. aureus* osteomyelitis model shows that MyD88 is also necessary to limit bacterial replicatio nd dissemination to other organs. Based on these data, I hypothesize that innate sensing of *S. aureus* by keletal cells *in vivo* impacts bacterial clearance and alters bone remodeling during osteomyelitis. To test this ypothesis we will induce osteomyelitis in wild-type mice and mice with skeletal cell-specific MyD88 deletion to) differentiate the kinetics of pathogen clearance from bone and bacterial dissemination to other organs, (ii) nvestigate bone remodeling alterations in cortical and trabecular bone using micro-computed tomography (microCT) analysis, and (iii) quantify osteoclast differentiation *in vivo* through histological assessment. Collectively, these studies will provide fundamental insight into how skeletal cells alter bone homeostasis, thereby elucidating fundamental mechanisms of osteo-immunologic crosstalk.

Kiran Khan, MD (Stanford University) - R01HL123305 (NHLBI)

Specific Aims Page 42

Research Plan
2. Specific Aims

Eukaryotic innate immune systems act as effective barriers to infection by microorganisms. Understanding the mechanisms that bacterial pathogens employ to circumvent innate immune systems will improve our ability to control disease. Plants and animals use specific pattern recognition receptors (PRRs) to recognize conserved molecules of microorganisms (known as PAMPs). Plants have numerous PRRs that can recognize specific virulence proteins specificall present in pathogens (known as Avr proteins). Many Gram-negative bacteria use type III protei secretion systems to inject effector proteins into host eukaryotic cells. We have shown that a primary role for many *Pseudomonas syringae* type III effectors is to suppress innate immunity. However, the enzymatic activities and the mechanisms that type III effectors use to suppress innate immunity are not well understood. Identifying the enzymatic activities of type III effectors and their substrates is essential to identify important components of innate immunity and to

Our *long-term goal* is to elucidate the molecular basis for suppression of innate immunity by type III effectors. The objective of this application is to identify targets of the *P. syringae* type III effector HopU1, a mono-ADP-ribosyltransferases (ADP-RTs), and to determine its roles in bacterial pathogenesis. *The central hypothesis of the proposed experiments is that the targets of the HopU1 ADP-RT type III effector will be components of innate immunity.* We formulated this hypothesis based on the literature and on our research on other type III effectors as well as our preliminary data showing that HopU1 suppresses outputs of innate immunity. Recently, we have shown that HopU1 can use several *Arabidopsis* RNA-binding proteins as high affinity substrates in *in vitro* ADP-RT assays. Based on our preliminary data, one of these proteins, *At*GRP7, plays a role in innate immunity. A major goal of this application is to elucidate the function of this protein as it relates to innate immunity. We are prepared to undertake the proposed research because we have extensive experience in manipulating type III systems, an we were among the first to report that certain type III effectors suppress innate immunity. In addition, our preliminary identification of HopU1's substrates has positioned us well to perform the experiments described in this application. Our research team includes experts in the following areas: type III secretion systems, proteomics and mass spectrometry, Affymetrix microarrays, plant glycine-rich RNA-binding proteins, and animal pathogen ADP-RTs. This qualified group of investigators will insure that our discoveries are linked to basic concepts of pathogenesis and immunity in both plants and animals.

The Specific Aims of this application are as follows:

***1.* Determine the molecular consequence of ADP-ribosylation on the function of *At*GRP7 and elucidate the role this protein plays in innate immunity.** Our *working hypothesis* of this aim is that *At*GRP7 binds to immunity-related RNAs to enhance the innate immune response and that ADP-ribosylation by HopU1 disrupts its function.

***2.* Identify additional substrates of HopU1 and verify their involvement in innate immunity.** Our *working hypothesis* is that the plant targets for the HopU1 ADP-RTs will be important components of plant innate immunity.

***3.* Analyze the affect that HopU1 has on host-microbe interactions.** Our *working hypothesi* of this aim is that HopU1 type III effector suppresses innate immunity. This is based on our preliminary data and in this aim we will determine to what extent this occurs with *HopU1*.

The proposed research is innovative because, to date, ADP-RTs have not been implicated in the suppression of innate immune surveillance systems. Moreover, RNA-binding proteins have not been described as substrates for ADP-RTs and, therefore, represent novel substrates for this important group of bacterial toxins. Collectively, we expect the outcomes of these experiments will greatly add to our understanding of the activities and roles of type III effectors, particularly in how they suppress innate immunity in eukaryotes.

SPECIFIC AIMS

Epidemiologic studies suggest that obese breast cancer patients experience poorer outcomes than their normal-weight counterparts (1-3), with a recent meta-analysis of 82 studies reporting that obese breast cancer cases have 41% higher total mortality than normal-weight cases (95% CI: 29%-53%) (1). It has been suggested that obese women may experience poorer outcomes, in part, due to the greater likelihood of dose reduction in chemotherapy (4-6). For most cytotoxic drugs, dose is calculated using body surface area (BSA); therefore, obese women would be expected to receive a higher absolute dose than normal weight women. However, due to concern about inducing chemotherapy-associated toxicity, clinicians are more likely to reduce the dose administered to obese women than normal-weight women (7), a finding replicated in several studies (8-12). While dose reductions may be warranted for reasons such as certaincomorbidities and toxicities, in 2012, the American Society of Clinical Oncology (ASCO) released guidelines urging clinicians to end this practice on the grounds of obesity, given research showing that obese women dosed at their BSA-determined dose are no more likely to experience toxicity than their normal weight counterparts (5). The guidelines were met with some criticism, citing the need for further research on adequate dosing (13).
Understanding the drivers of dose reductions may help better inform our understanding of this practice and efforts to disseminate guidelines; however, we know little about factors driving dose

Two major questions pertaining to the ASCO guidelines remain unanswered. First, while these guidelines suggest that chemotherapy dose reductions among obese patients may, in part, explain the association between obesity and breast cancer survival (5), this question has not been evaluated. **Demonstrating that dose reductions contribute to the associations between obesity and adverse outcomes would strengthen the case for these guidelines, and would provide a clear point of intervention to improve prognosis for obese women.** Second, the guidelines acknowledge that data pertaining to risk of toxicity are extremely limited with regard to *more severe obesity*, and in the real-world context of the presence of obesity-associated *comorbid conditions* (5). **If women with larger body sizes receiving the BSA-determined dose of chemotherapy do not experience excess toxicity as compared to normal weight women, this would provide further evidence in favor of the ASCO guidelines.**

Our interdisciplinary team, with expertise in epidemiology, pharmacology, and breast medical oncology is uniquely positioned to address these questions. Taking advantage of the rich data of two integrated healthcare delivery systems, Kaiser Permanente Northern California (KPNC) and Group Health (GH), in nearly 34,000

1. Identify predictors of chemotherapy dose intensity, focusing on whether body size is a principal driver of dose reduction, and whether other predictors of dose reduction vary by body mass index. Factors to be considered include patient-level factors (e.g., age, race/ethnicity, level of obesity, comorbidities such as diabetes, kidney disease, or cardiovascular disease), disease characteristics (e.g., stage, nodal involvement, grade, hormone receptor status), treatment, and provider-level factors (e.g., practice size, gender, age, provider-patient racial concordance).
2. Evaluate associations between body size and breast cancer recurrence and survival, focusing on the role of chemotherapy dosing as a mediator of these associations.
3. Among women identified as receiving BSA-expected dosing of chemotherapy, evaluate the association between BMI and toxicity; this will reveal if women receiving BSA-determined dosing at higher BMIs experience more or less toxicity than their non-obese counterparts. Toxicities include neutropenia and neuropathy, cardiotoxicity, renal impairment, and hepatic impairment.

Understanding these points will better inform clinical management for the estimated 102,000 obese women diagnosed with breast cancer each year in the United States (14, 15). It is critical that we address this issue, given that approximately 40% of adult women in the United States are obese and the prevalence of obesity continues to rise among women (14). With detailed information on treatment, comorbid conditions, and toxicities from KPNC and GH, as well as follow-up
address these questions about which little is known
knowledge, this is only such setting in which such a
expertise, and access to this rich data source, our
timely avenue of research.

Specific Aims: Answers Key Questions

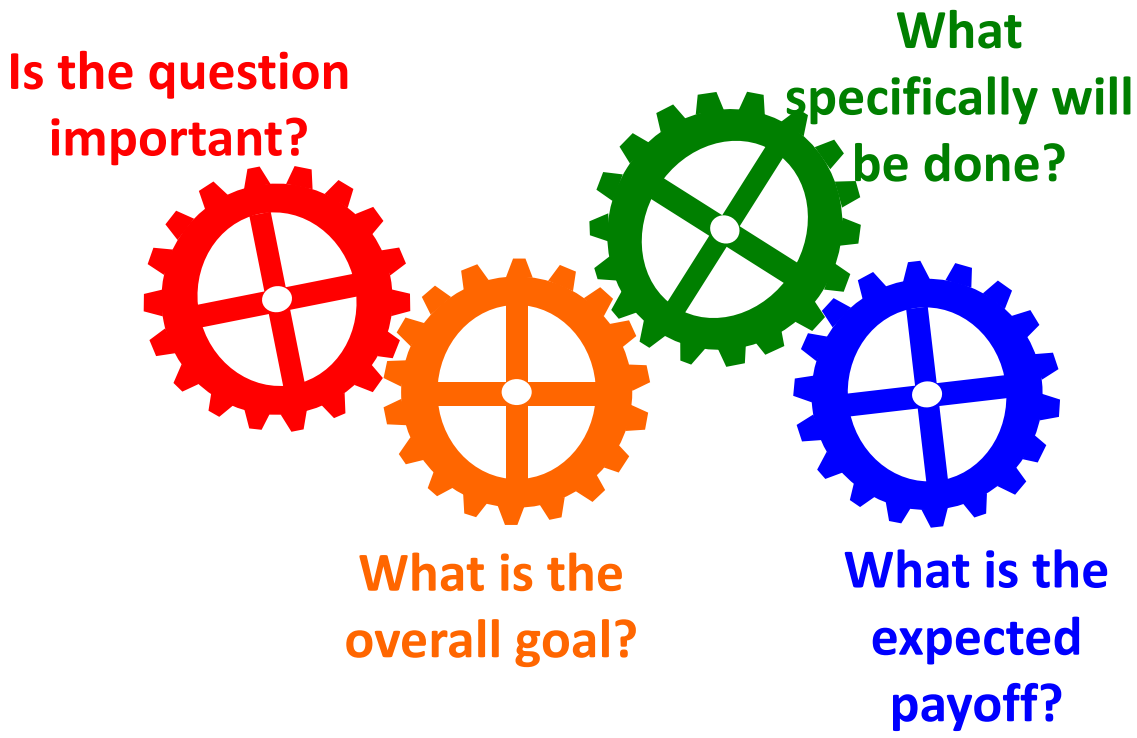
Is the question important?

What specifically will be done?

What is the overall goal?

What is the expected payoff?

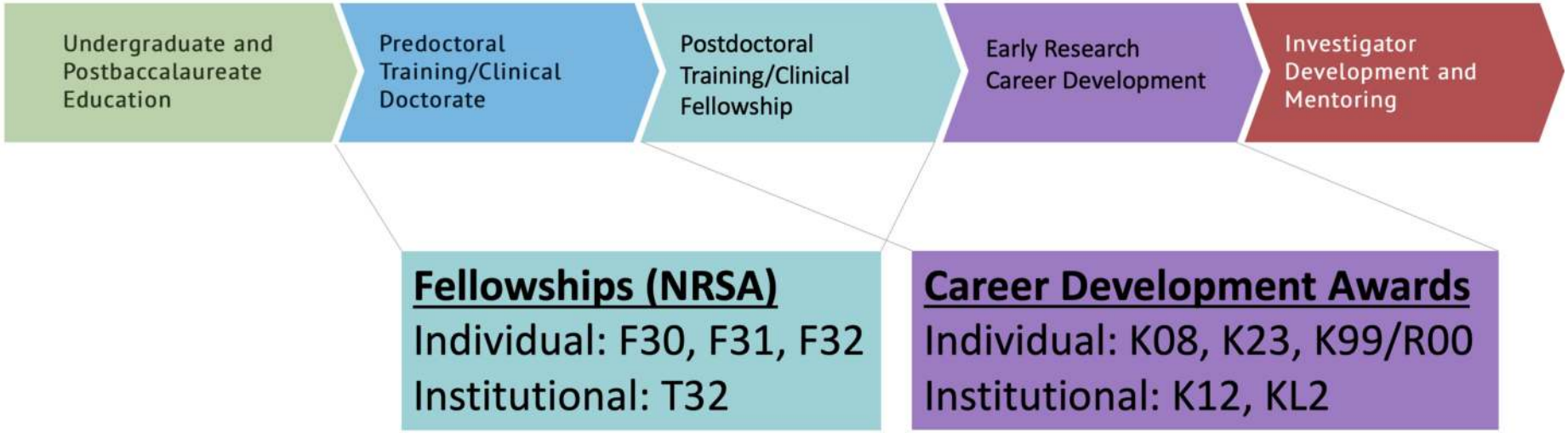
Specific Aims: Gearing Up

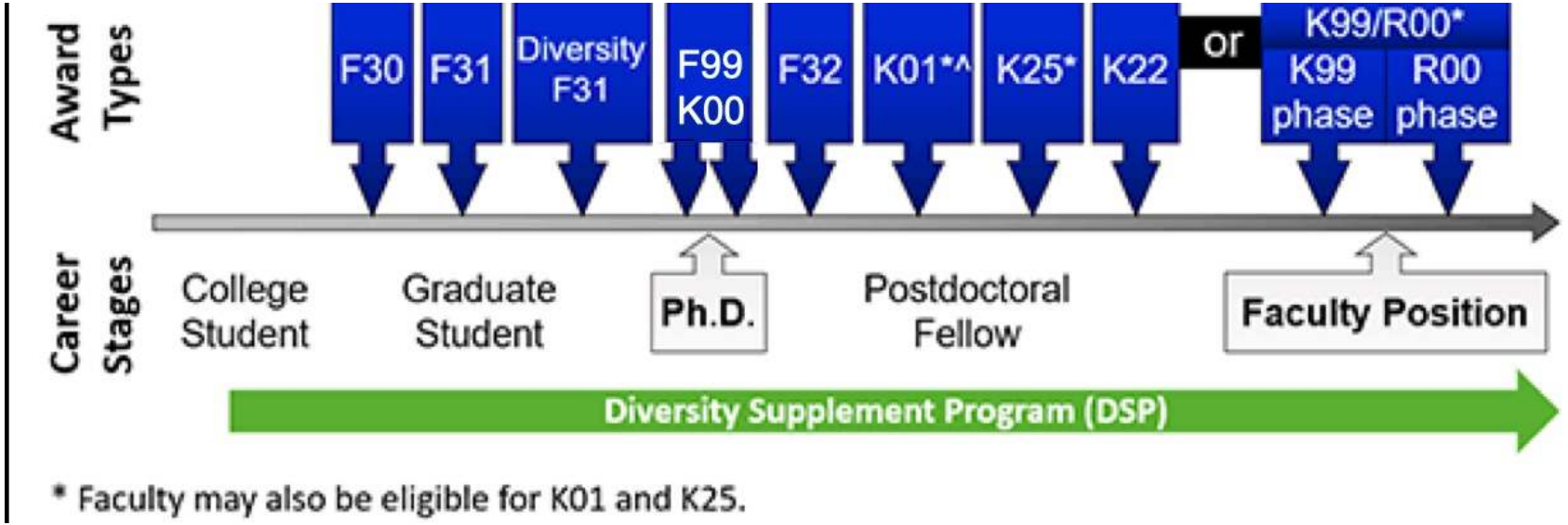


Lesson 3:

Identify the right funding mechanism for you.

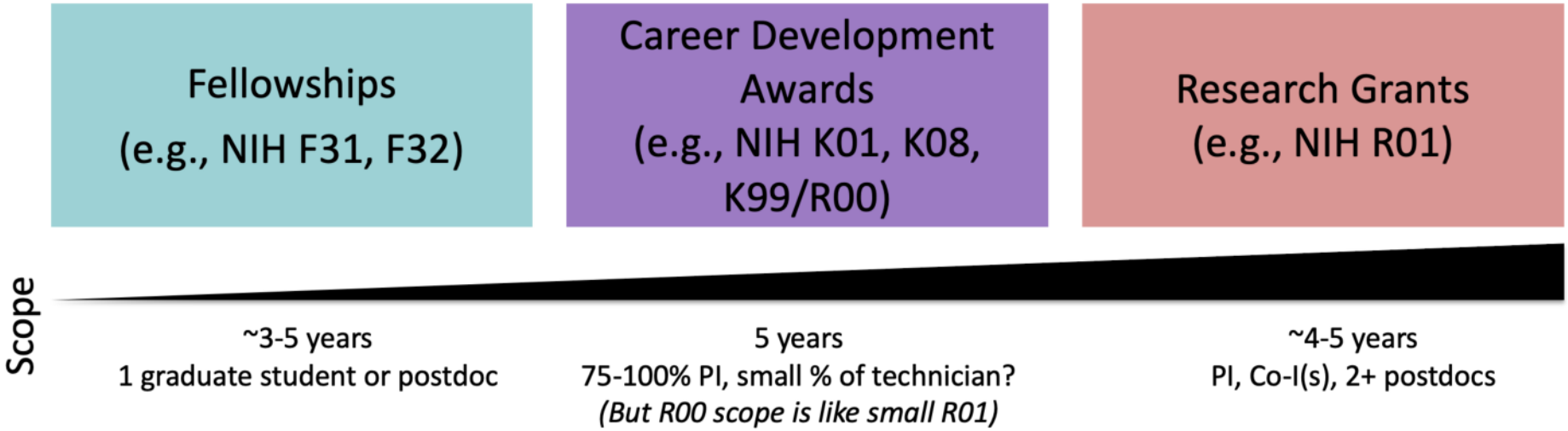
NIH programs prepare the skilled, creative and diverse biomedical researchers of tomorrow



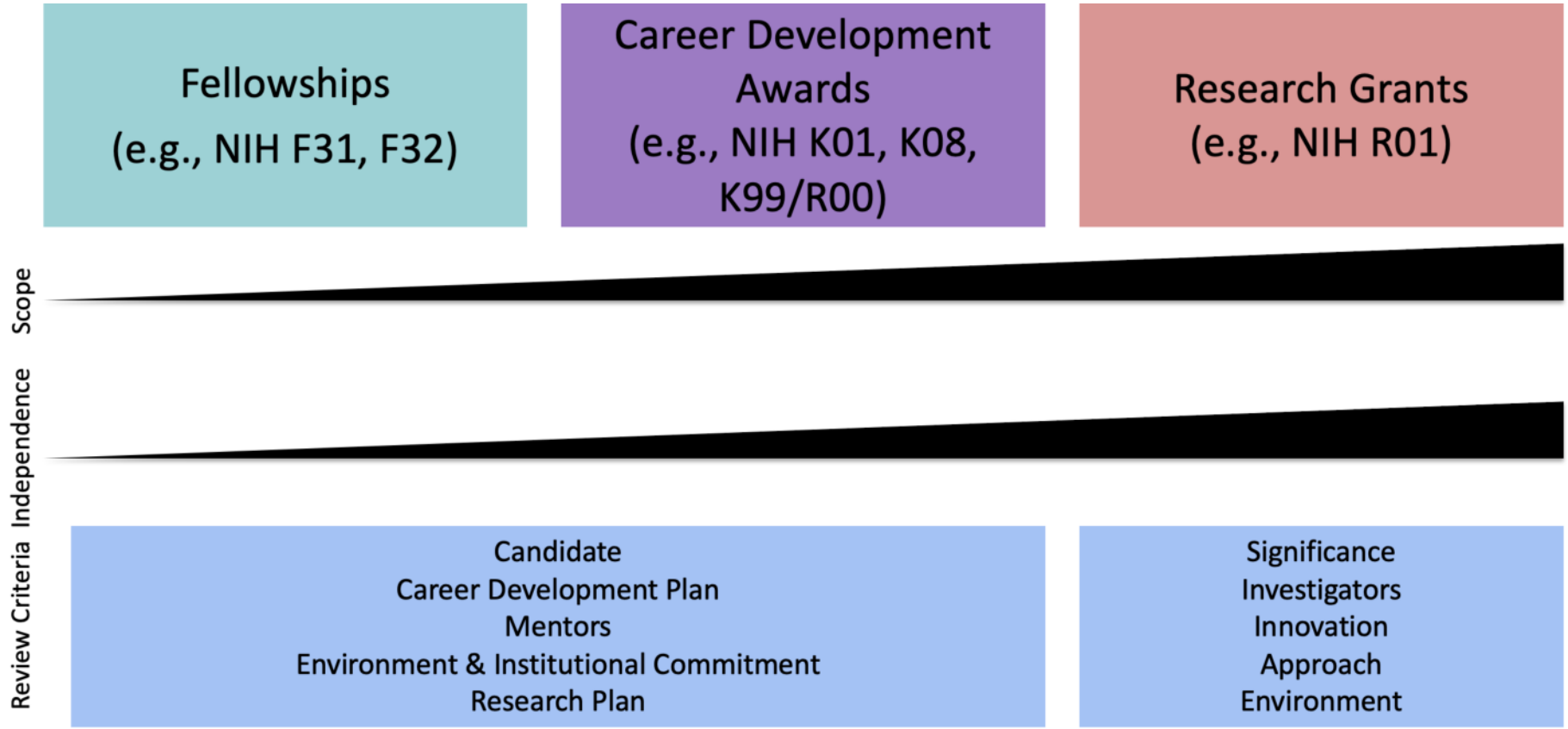


* Faculty may also be eligible for K01 and K25.

Comparing different types of grants



Comparing different types of grants



Open a relevant Funding Opportunity Announcement (FOA):

- F31: https://grants.nih.gov/grants/guide/pa-files/PA-21-051.html
- F32: https://grants.nih.gov/grants/guide/pa-files/PA-21-048.html
- K99/R00: https://grants.nih.gov/grants/guide/pa-files/PA-20-188.html
- K08: https://grants.nih.gov/grants/guide/pa-files/PA-20-203.html

NIH Fellowships

Enhance the research training of promising candidates who have the *potential* to become productive, independent investigators

- Due Dates: April, August, & December *
- Eligibility: U.S. citizen or permanent resident
- Duration (w/T32): F31: <5 years; F32: <3 years
- Effort: 100%; but 25% clinical activities OK (NOT-OD-17-095)
- Payback requirement: First 12 months
- NOT-OD-21-074: Childcare costs ($2,500)

NIH K Awards

Provide individual and instructional research training opportunities designed to *launch* independent careers

- Due Dates: February, June, & October *
- Eligibility: U.S. citizen or permanent resident, except parent K99/R00
- Duration: 3-5 years
- Effort: 75%

* Some FOAs have different due dates

Funding Opportunity Announcement (FOA)

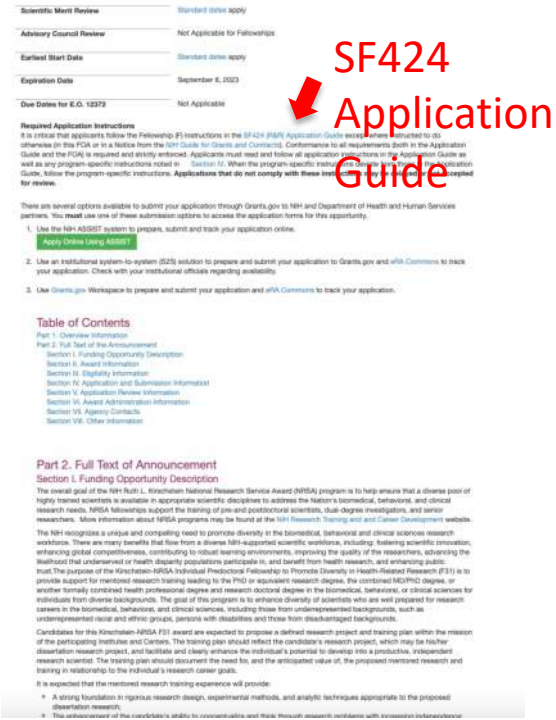
Instructions for applying

Department of Health and Human Services

Part 1. Overview Information

Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research (Parent F31-Diversity)

PA-21-052



SF424 Application Guide

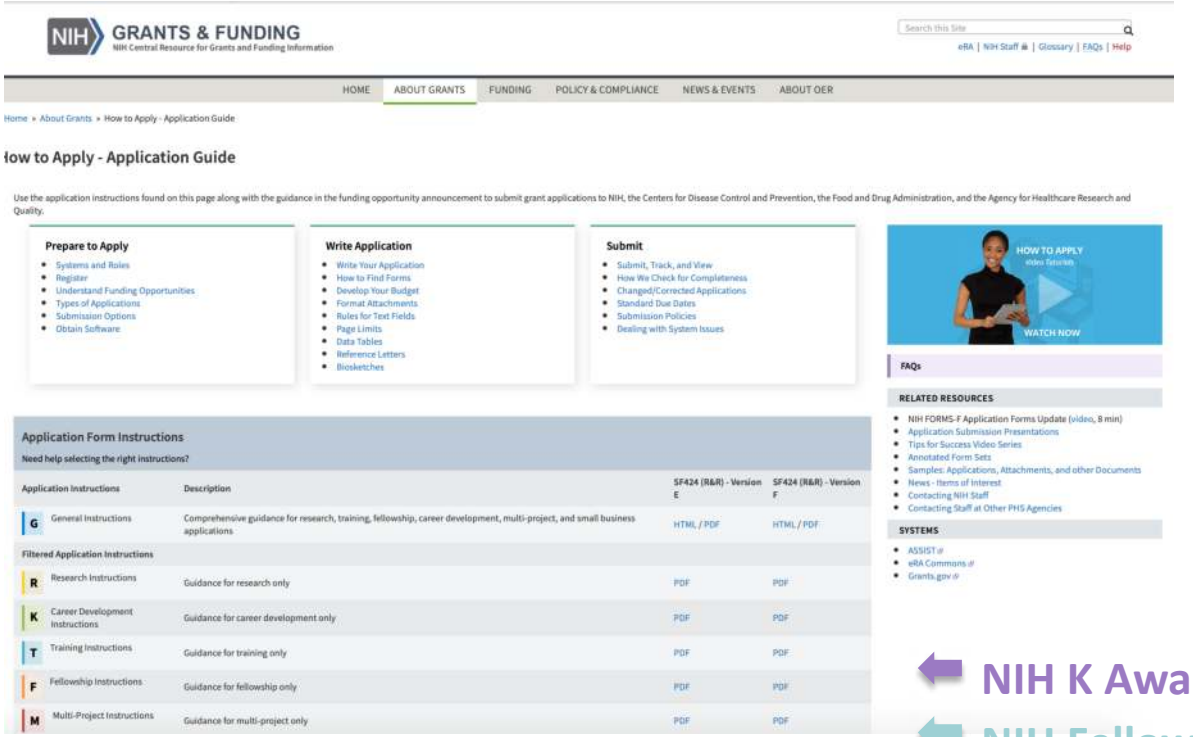
Table of Contents

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Goes on and on….

SF424 Application Guide



NIH K Award

NIH Fellowship

https://grants.nih.gov/grants/how-to-apply-application-guide.html

Parent vs Diversity Funding

Funding Opportunity Title

Mentored Research Scientist Development Award (Parent K01 - Independent Clinical Trial Not Allowed)

Activity Code

K01 Research Scientist Development Award - Research & Training

Announcement Type

Reissue of PA-19-126

Related Notices

- **June 5, 2020** - Notice of Special Interest (NOSI) of NIDCR in Supporting Dental, Oral, and Craniofacial Research Using Bioinformatic, Computational, and Data Science Approaches. See Notice NOT-DE-20-006.

Funding Opportunity Announcement (FOA) Number

PA-20-190

Funding Opportunity Title

Mentored Career Development Award to Promote Faculty Diversity in Biomedical Research (K01 Independent Clinical Trial Required)

Activity Code

K01 Research Scientist Development Award - Research & Training

Announcement Type

Reissue of RFA-HL-18-027

Related Notices

- **March 10, 2020** - Reminder: FORMS-F Grant Application Forms & Instructions Must be Used for Due Dates On or After May 25, 2020- New Grant Application Instructions Now Available. See Notice NOT-OD-20-077.
- January 22, 2020 - Additional Guidance on the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research. See Notice NOT-OD-20-058.
- **November 22, 2019** - Notice of NIH's Interest in Diversity. See Notice NOT-OD-20-031.
- **August 23, 2019** - Clarifying Competing Application Instructions and Notice of Publication of Frequently Asked Questions (FAQs) Regarding Proposed Human Fetal Tissue Research. See Notice NOT-OD-19-137.
- **July 26, 2019** - Changes to NIH Requirements Regarding Proposed Human Fetal Tissue Research. See Notice NOT-OD-19-128.
- **July 22, 2019** - Requirement for ORCID iDs for Individuals Supported by Research Training, Fellowship, Research Education, and Career Development Awards Beginning in FY 2020. See Notice NOT-OD-19-109.
- **November 26, 2018** - NIH & AHRQ Announce Upcoming Updates to Application Instructions and Review Criteria for Career Development Award Applications. See Notice NOT-OD-18-229.

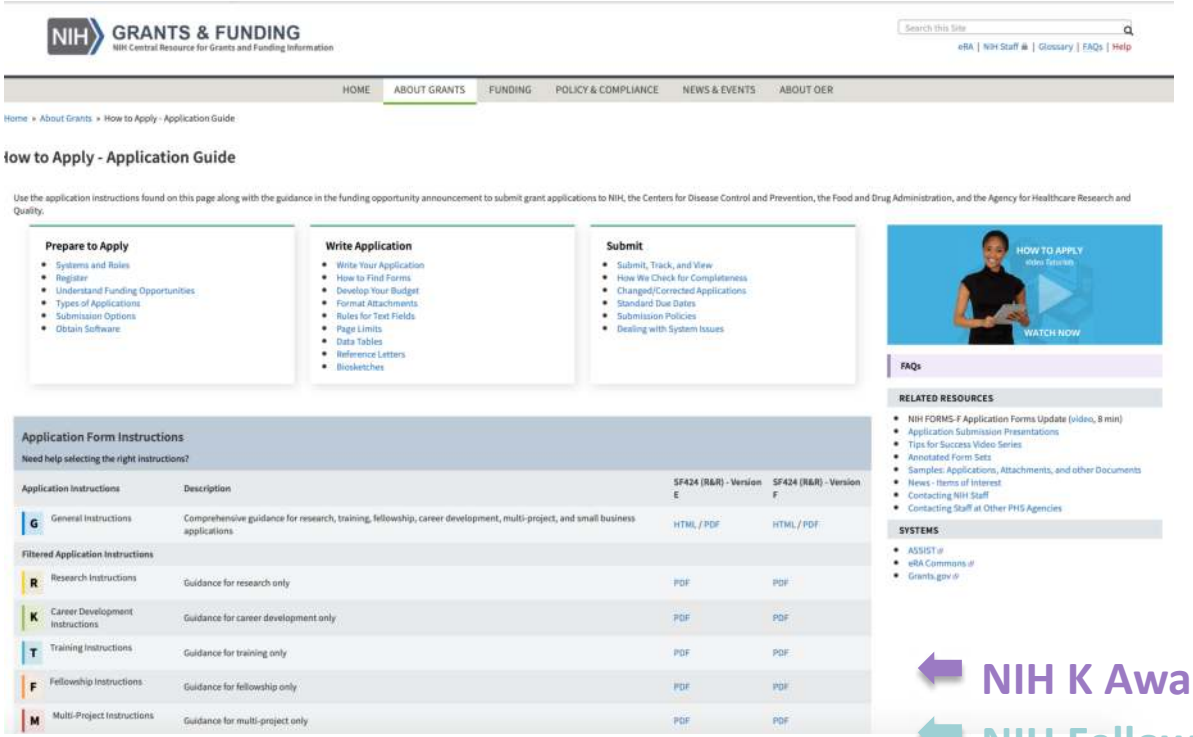
Funding Opportunity Announcement (FOA) Number

RFA-HL-19-025

Lesson 4:

Understand the application components and review criteria.

SF424 Application Guide



NIH K Award

NIH Fellowshi

https://grants.nih.gov/grants/how-to-apply-application-guide.html

Application Components

- Specific Aims (1 page)
- Candidate's background
- Career Goals &Objectives
- Candidate's Plan for Career Development
- Research Strategy (Together = 12pages)
- Bibliography
- Biosketch (5 pages)
- Budget (long…work w/RMG)
- Equipment
- Facilities and other resources
- Project narrative/project summary (~few lines to a few paragraphs)
- Resource sharing
- Collaborators, contributors, consultants (limited to 6pages)
- Mentor/collaborator biosketches
- Training in Responsible Conduct of Research (1 page)
- Plans and Statement of Mentors(6 pages)
- Institutional commitment (1page)
- Description of Institutional Environment (1page)
- Letters of reference(3-5)
- Vertebrate animals
- Protection of human subjects
- Inclusion statement – women, children, etc.
- Biosafety
- PI Waiver (as early as possible)
- Grants office internal deadline (5 business days prior to grant due date)

Application Components

Core Document - Needs time and several rounds of iterative feedback
Letters or Other Supporting Documents: Information needed from Mentors or Others
Boiler document - Takes time but not needing much iterative feedback

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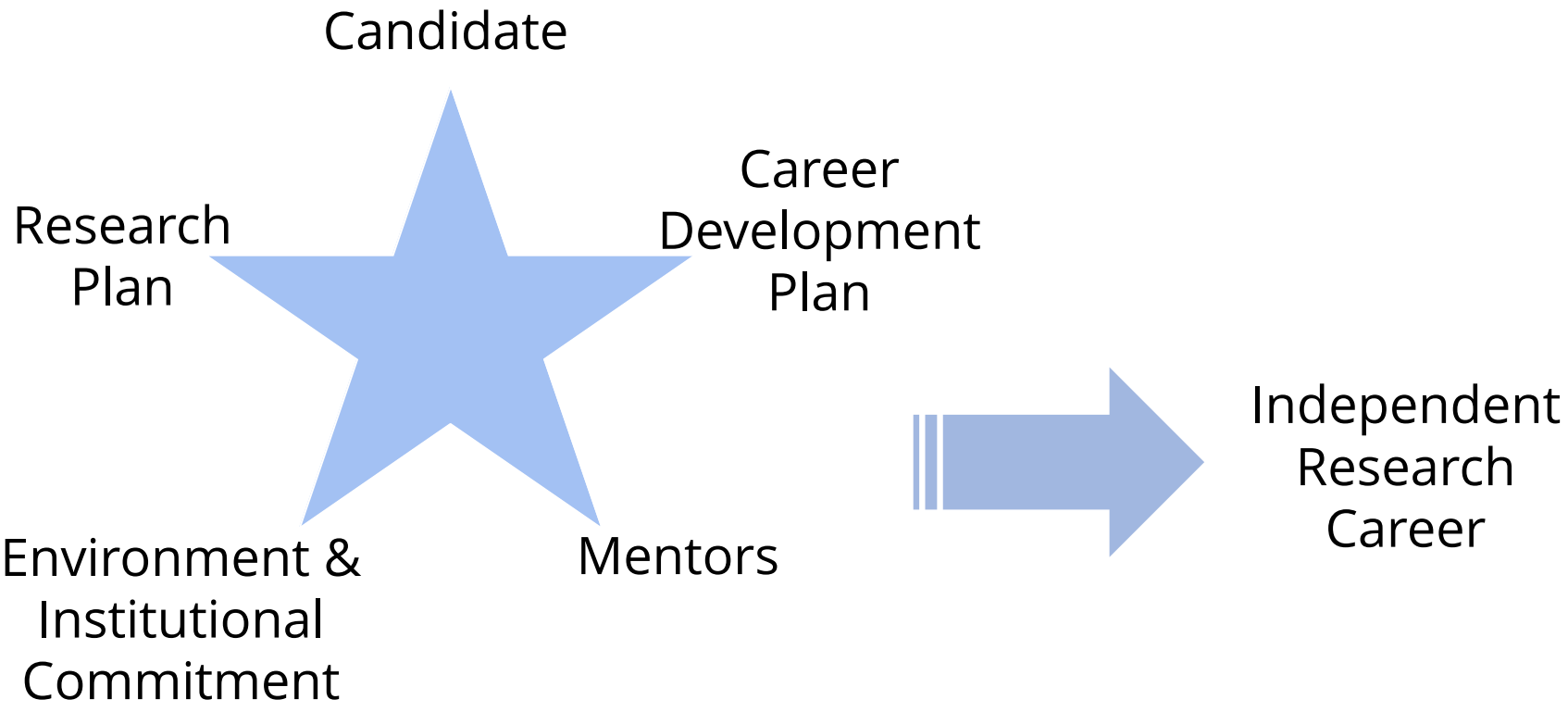
Key Required Documents

Required documents for K Awards *	Page Limits
Specific Aims	1
Research Strategy *	* 12 pages combined
Candidate's Background *	
Career Goals and Objectives *	
Candidate's Plan for Career Development / Training Activities During Award Period *	
Plans and Statements of Mentor and Co-mentor(s)	6
Letters of Support from Collaborators, Contributors, and Consultants	6
Description of Institutional Environment	1
Institutional Commitment	1
Letters of Reference (3-5)	2 each
Biographical Sketch – Yours, Mentors, Advisors	5 each

Scored Review Criteria



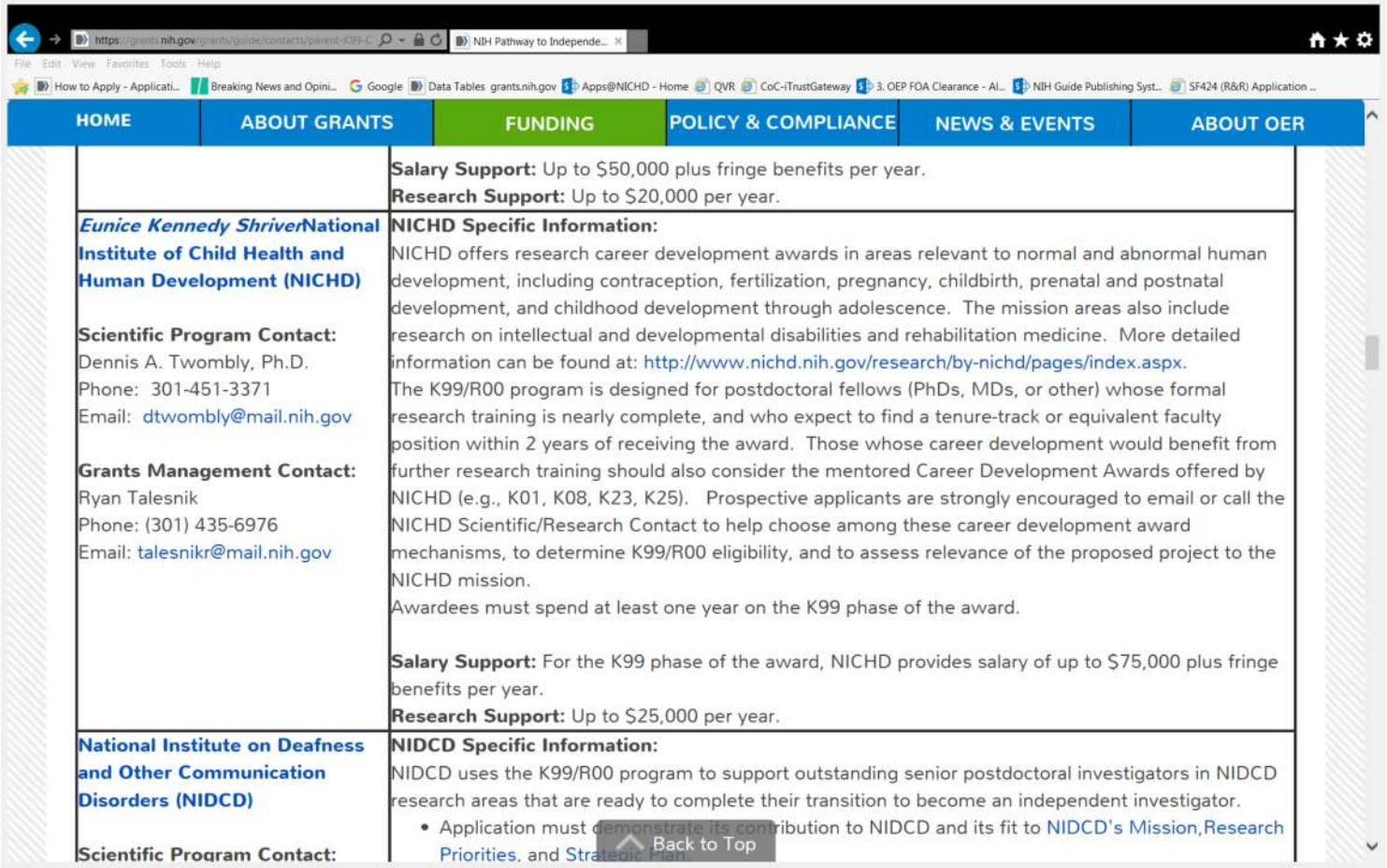
Lesson 5:

Pick the right institute.

National Institutes of Health

- Organized into 27 different institutes and centers
- Each institute and center has a specific mission and research goals

K99 Table of IC Specific Information



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	Salary Support: Up to $50,000 plus fringe benefits per year. **Research Support:** Up to $20,000 per year.
***Eunice Kennedy Shriver*National Institute of Child Health and Human Development (NICHD)** **Scientific Program Contact:** Dennis A. Twombly, Ph.D. Phone: 301-451-3371 Email: dtwombly@mail.nih.gov **Grants Management Contact:** Ryan Talesnik Phone: (301) 435-6976 Email: talesnikr@mail.nih.gov	**NICHD Specific Information:** 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: http://www.nichd.nih.gov/research/by-nichd/pages/index.aspx. 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. **Salary Support:** For the K99 phase of the award, NICHD provides salary of up to $75,000 plus fringe benefits per year. **Research Support:** Up to $25,000 per year.
National Institute on Deafness and Other Communication Disorders (NIDCD) **Scientific Program Contact:**	**NIDCD Specific Information:** 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. • Application must demonstrate its contribution to NIDCD and its fit to NIDCD's Mission, Research Priorities, and Strategic Plan.

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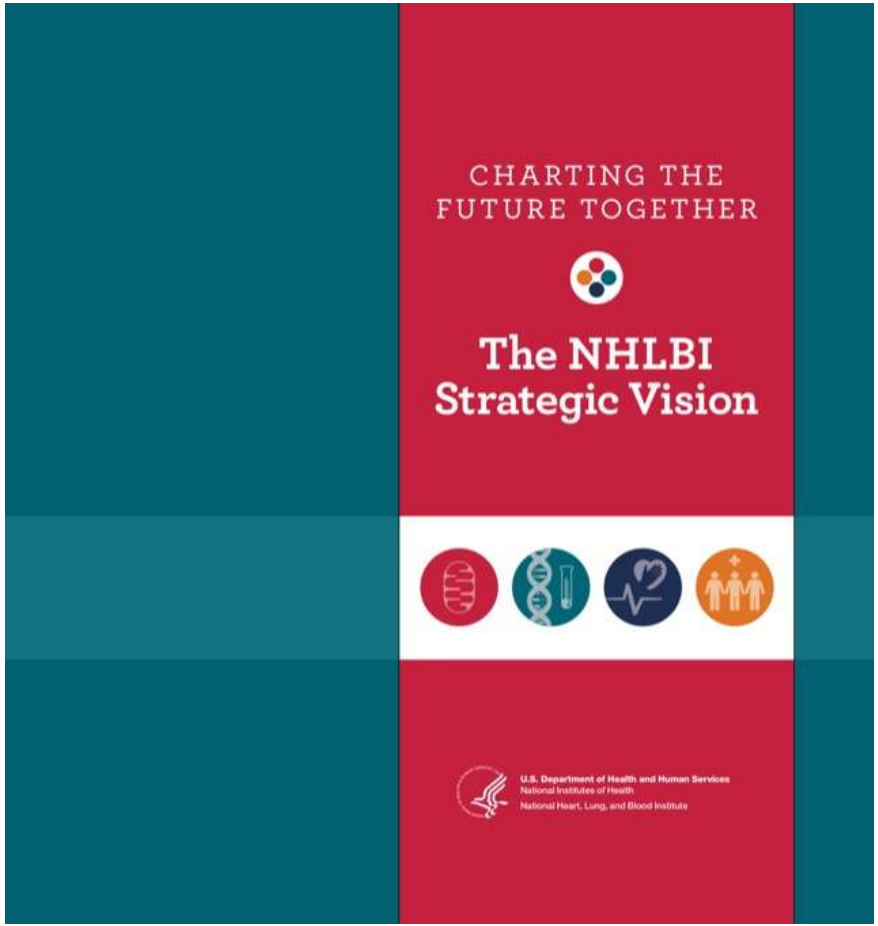
Read IC's strategic visions



1. Understand normal biological function and resilience
2. Investigate newly discovered pathobiological mechanisms important to the onset and progression of HLBS diseases
3. Investigate factors that account for differences in health among populations
5. Develop and optimize novel diagnostic and therapeutic strategies to prevent, treat, and cure HLBS diseases
6. Optimize clinical and implementation research to improve health and reduce disease
7. Leverage emerging opportunities in data science to open new frontiers in HLBS research

Read IC's strategic visions (& related documents)

> Ethn Dis. 2019 Feb 21;29(Suppl 1):57-64. doi: 10.18865/ed.29.S1.57. eCollection 2019.

The National Heart, Lung, and Blood Institute Strategic Vision Implementation for Health Equity Research

George A Mensah [1], Catherine M Stoney [2], Michelle M Freemer [3], Sharon Smith [4], Michael M Engelgau [1], W Keith Hoots [4], James P Kiley [3], David C Goff [2]

Affiliations + expand

PMID: 30906150 PMCID: PMC6428185 DOI: 10.18865/ed.29.S1.57

Free PMC article

Abstract

The National Heart, Lung, and Blood Institute (NHLBI) provides global leadership for a research, training, and education program to promote the prevention and treatment of heart, lung, and blood diseases and enhance the health of all individuals so that they can live longer and more fulfilling lives. Inherent in this mission is the commitment to advance health equity research as an avenue for enhancing the health of all individuals. Additionally, the four goals and eight research objectives of the NHLBI Strategic Vision directly support the commitment to health equity. In this article, we present selected examples of the NHLBI Strategic Vision implementation approaches for advancing health equity research in our mission areas of heart, lung, and blood diseases. Examples of diseases for which the burden of health inequities and our strategic vision implementation approaches are discussed include hypertension, heart failure, vascular dementia, asthma, and sickle cell disease. Examples are provided of new avenues of Institute-solicited research to stimulate and address compelling scientific questions and critical challenges to advance health

Circulation Research
Volume 124, Issue 4, 15 February 2019; Pages 491-497
https://doi.org/10.1161/CIRCRESAHA.118.314338

American Heart Association.

SPECIAL ARTICLE

Implementing the National Heart, Lung, and Blood Institute's Strategic Vision in the Division of Cardiovascular Sciences

David C. Goff Jr, Denis B. Buxton, Gail D. Pearson, Gina S. Wei, Teri E. Gosselin, Ebyan A. Addou, Catherine M. Stoney, Patrice Desvigne-Nickens, Pothur R. Srinivas, Zorina S. Galis, Charlotte Pratt, Brian K. Kit, Christine Maric-Bilkan, Holly L. Nicastro, Renee P. Wong, Vandana Sachdev, Jue Chen, Lawrence Fine, and for the writing group of Division of Cardiovascular Sciences' Strategic Vision Implementation Plan.

ABSTRACT: As we commemorate the 70th anniversary of the National Heart, Lung, and Blood Institute and celebrate important milestones that have been achieved by the division of cardiovascular sciences, it is imperative that division of cardiovascular sciences and the Extramural Research community at-large continue to address critical public health challenges that persist within the area of cardiovascular diseases. The National Heart, Lung, and Blood Institute Strategic Vision, developed with extensive input from the extramural research community and published in 2016, included overarching goals and strategic objectives that serve to provide a general blueprint for sustaining the legacy of the institute by leveraging opportunities in emerging scientific areas (eg, regenerative medicine, omics technology, data science, precision medicine, and mobile health), finding new ways to address enduring challenges (eg, social determinants of health, health inequities, prevention, and health promotion), and training the next generation of heart, lung, blood, and sleep researchers.

Why do we care so much about the IC's strategic visions?

Alignment with NIDA: My current work and the proposed project closely aligns with NIDA's mission and strategic plan. My research is especially relevant to developing improved strategies to prevent the consequences of drug use (Goal 2), improving treatments to help achieve and maintain meaningful, sustained recovery (Goal 3), and increasing the public impact of NIDA research (Goal 4). This K99/R00 proposal combines multiple data sources (corporate data warehouses, public- and restricted-access data sets, and large claims databases) with machine learning and advanced causal inference methods to identify ways of equitably increasing access to and retention in opioid use disorder treatment. My project is responsive to NIDA's priorities regarding machine learning and big data projects (e.g., NOT-DA-19-041 and PAR-19-368).

Lesson 6:

Talk to your Program Officer (PO).

Why contact your program officer? To...

- Help you identify which grant/funding opportunity to apply for
- Verify that your proposal fits within the mission of the institute
- Discuss whether your research is considered a clinical trial, and to discuss the outcome of a grant (i.e. to discuss your score and comments).

How to find your PO?

- Look up or download the current FOA for the grant you want to apply for.
- Scroll down and click on “Section VII: Agency Contacts.”
- Click on “Table of IC-Specific Information, Requirements, and Staff Contacts.”
- Scroll down to your institute, and contact the “Scientific Program Contact.”
- Note, there may be a few program contacts available, so pick the division contact that is most applicable to your proposal.

Lesson 7:

Apply as early as possible.

Average Timeline

- 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!

Timeline of an application funded on the first try

- 9/10/2018 (-397 days): First day as a post-doc.
- 12/11/2018 (-305 days): Convinced by MMG to apply for a K99/R00.
- 6/15/2019 (-119 days): First shareable version of a Specific Aims page is finished.
- 6/19/2019 (-115 days): Phone call with my program official (PO) to discuss my Specific Aims page and confirm eligibility.
- 10/1/2019 (-11 days): Final version of the application is sent to Stanford Research Management Group (RMG) for review and submission.
- 10/11/2019 (-1 days): Stanford RMG sends the application to the NIH.
- **10/12/2019 (0 days): K99/R00 application is due.**
- 2/7/2020 (+118 days): Post-submission material is requested by my PO.
- 2/13/2020 (+124 days): Post-submission material (additional publications) is sent to my PO.
- 3/19/2020 (+159 days): Study section meets to discuss all K99/R00s.
- 3/19/2020 (+159 days): Impact score is updated online.
- 4/7/2020 (+178 days): Summary statement is available online.
- 4/7/2020 (+178 days): Receive a request from my PO to respond to critiques raised in the summary statement.
- 4/9/2020 (+180 days): Phone call with my PO to discuss the parameters of my response to the summary statement.
- 4/14/2020 (+185 days): Response to the summary statement is sent to my PO.
- 5/12/2020 (+213 days): NIDA council meeting.
- 5/14/2020 (+215 days): PO informs me just-in-time (JIT) information will be requested by NIDA Grants Management Branch.
- 5/27/2020 (+228 days): Submitted JIT information through Stanford RMG.
- 5/28/2020 (+229 days): JIT information is due.
- 6/12/2020 (+244 days): Status (on eRA Commons) updated to “Awarded.” NOA uploaded a couple hours later.
- 7/1/2020 (+263 days): Project start date.

Source: https://mathewkiang.com/2020/06/12/applying-for-a-k99/

My timeline (to date)

- February 2020: K01 application submitted
- June 2020: K01 review results posted (not discussed)
- July 2020: K01 summary statement posted
- February 2021: K99/R00 submitted *(first submission)*
- July 2021: K99/R00 summary statement posted
- November 2021: K99/R00 submitted *(resubmission)*
- March 2022: K99/R00 review results/score posted
- April 2022: K99/R00 summary statement posted
- May 2022: K99/R00 JIT documents submitted
- June 2022: K99/R00 review council meets and application is updated to “Pending
- August 22, 2022: K99/R00 Notice of Award (NOA) posted
- September 1, 2022 Official K99 start date

Lesson 8:

Give yourself plenty of time.

Lots of other information required too!

Project Summary / Abstract

Project Narrative

Facilities & Other Resources

Equipment

Biographical Sketches

Current and Pending Support for Mentors / Co-Mentors

Budget and Budget Justification

Training in the Responsible Conduct of Research

Authentication of Key Biological and/or Chemical Resources, if applicable

Vertebrate Animals, if applicable

Human Subject Form, if applicable

Select Agent Research, if applicable

Resource Sharing Plan, if applicable

Goes on and on….

NOT an all-nighter!

4+ months before deadline

- Draft Specific Aims
- Draft Biosketch
- Outline training plan
- Contact mentoring team & letter writers

3 months before deadline

- Refine Specific Aims & training plan
- Draft Significance & Approach
- Draft all career development docs
- Contact Program Officer
- Incorporate feedback on drafts

2 months before deadline

- Incorporate feedback on all drafts
- Finalize all letter writer docs & commitment
- Gather institutional support documents
- Boiler docs – Facilities & Other Resources / Equipment

1 month before deadline

- Start ASSIST application
- Finalize all docs

Acknowledgments:

Stanford BIOSCIENCES GRANT WRITING ACADEMY

@SUGrantWriting

grantwriting.stanford.edu

THANK YOU!

hmagid@stanford.edu

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Career (K) Kiosk

K01

Mentored Research Scientist Career Development Award

For support of a postdoctoral or early career research scientists committed to research, in need of both advanced research training and additional experience.

K08

Mentored Clinical Scientist Research Career Development Award

To provide the opportunity for promising clinician scientists with demonstrated aptitude to develop into independent investigators, or for faculty members to pursue research, and aid in filling the academic faculty gap in health profession's institutions.

K23

Mentored Patient-Oriented Research Career Development Award

To provide support for the career development of clinically trained professionals who have made a commitment to patient-oriented research, and who have the potential to develop into productive, clinical investigators.

K99/ R00

Pathway to Independence Award

To support both an initial mentored research experience (K99) followed by independent research (R00) for highly qualified, postdoctoral researchers, to secure an independent research position. Award recipients are expected to compete successfully for independent R01 support during the R00 phase.

Active FOAs (Parent & IC specific) can be found at: https://researchtraining.nih.gov/programs/career-development

At that website click on each K award type to view active FOAs

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Pathway to Independence Award

K99/R00: Goal to facilitate ***transition*** from a mentored postdoctoral research position to an independent research position with ***independent NIH research support*** at an earlier stage than the current norm

Supports protected time (75%) in 2 distinct phases:

K99 – Phase 1- 2 years

- Mentored: must be affiliated with an institution
- Within 4 years of attaining PhD or completing clinical training
- 2007 awardees: 94.7% transition to R00; 2014 awardees 87.6% transition to R00.

R00 – Phase 2 (3 years)

- Independent (tenure-track or equivalent),own lab limited teaching and/or clinical responsibilities to assist pathway to next independent award.
- 'Quality' of tenure-track offer administratively reviewed by NIH staff before R00 awarded

No U.S. citizenship requirement for applicants to the **parent K99 (**PA-20-187; PA-20-188; PA-20-189)

NIAID Physician Scientist K99-R00: PAR-20-209; PAR-20-210; NOT-AI-19-034; **Requires 50% effort;** *no U.S. citizenship requirement*

NIDCR Dual Degree Dentist Scientist K99-R00 (PAR-18-432; PAR-19-144; PAR-19-141) *no U.S. citizenship requirement*.

Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative K99-R00 to promote diversity (RFA-NS-19-043 RFA-NS-19-044) ***requires*** *citizenship/permanent resident status*.

Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Postdoctoral Career Transition Award to Promote Diversity *K99-R00 requires* *citizenship/permanent resident status;* first due date February 12th 2020 (PAR-19-343); **Institutional UE5 Co-operative Agreement** due date November 15th 2019 (PAR-19-342) provides courses for skills development & mentoring.

Due to COVID two cycle extension of eligibility announced for Parent K99 NOT-OD-20-158; NIDCR K99 NOT-DE-20-031; Mosaic K99 NOT-GM-20-051

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K01, K08 and K23 FOAs with different requirements

Funding Opportunity Announcements (FOAs) for K Awards will :

Require PD/PI to conduct an independent clinical trial

- PA-20-176 (K01;14 IC)
- PA-20-202 (K08;15 IC)
- PA-20-206 (K23;17 IC)

K applicant/awardee has primary or lead responsibility for conducting & executing the trial (Funding is from the K award & may be an ancillary or feasibility study)

Permit clinical trial research experience but will NOT permit an independent clinical trial

- PA-20-190 (K01;16 IC)
- PA-20-203 (K08; 20 IC)
- PA-20-205 (K23; 19 IC)

K applicant/awardee may propose research experience in a clinical trial led by the K award mentor or co-mentor.

Permit Basic Experimental Studies with Humans (BESH)

- PA-20-191 (K01; 9 IC)
- PA-20-201 (K08; 13 IC)
- PA-20-204 (K23; 12 IC)

K applicant/awardee may propose basic science experimental studies involving humans which can be "prospective basic science studies involving human participants."

Timeline for Individual K Applications



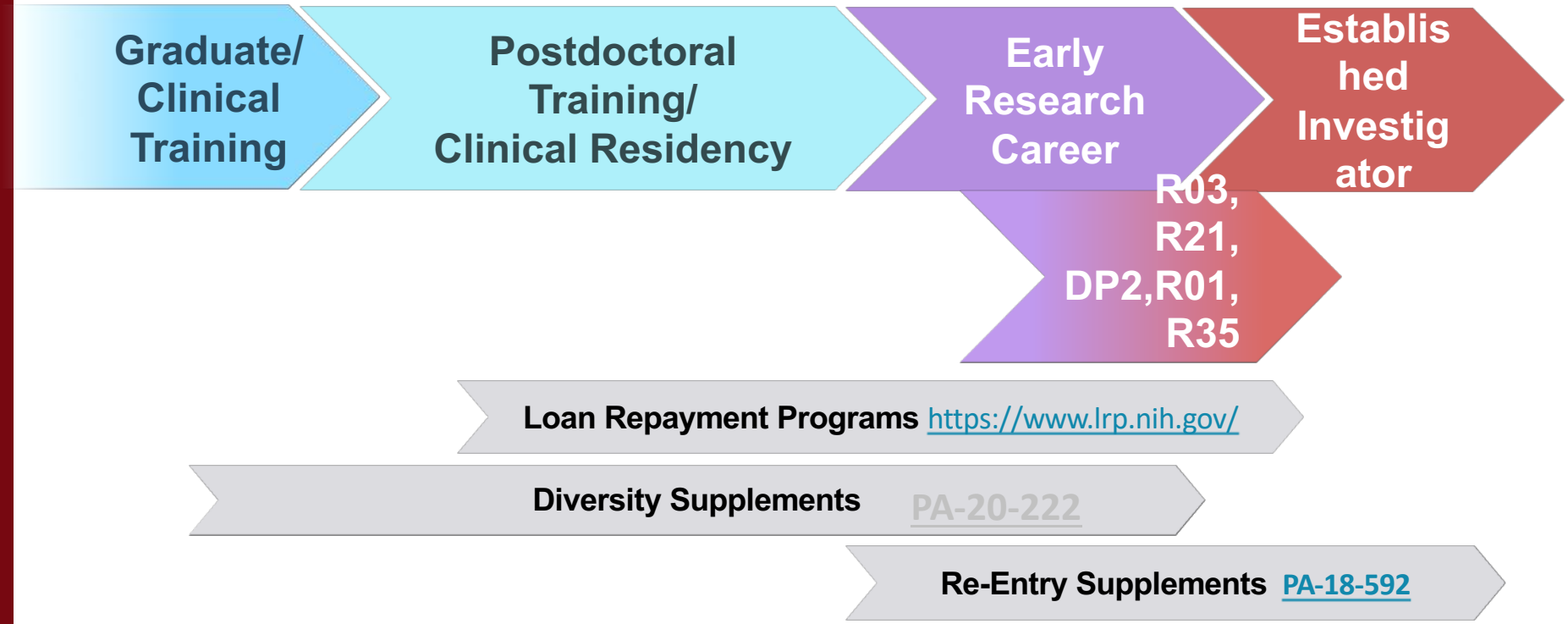

RECEIPT DATE	REVIEW	COUNCIL	AWARD DATE
Feb 12 Resubmission Mar 12	Jun/July	October	December
Jun 12 Resubmission Jul 12	Oct/Nov	January	April
Oct 12 Resubmission Nov 12	Feb/Mar	May	July

Institutional Mentored K Awards

K12/KL2: Institutional programs to support scholar training for careers in **specified research areas** of interest to one or more NIH Institutes and Centers (IC)

- IRACDA (Institutional Research & Academic Career Development Awards K12: PAR-19-366 postdoctoral research at a research-intensive institution & teaching/mentoring undergraduates at partner institutions focused on students from groups underrepresented in biomedical research (Due dates 11/13/19; 10/01/20; 10/01/21).
- Some K12/KL2 programs are primarily for **clinicians or clinically relevant research:**
  - Building Interdisciplinary Research in Womens' Health (BIRWCH) K12 RFA-OD-19-020
  - NCATS KL2 PAR-18-940.
- Prepare PhDs/clinicians for independent research careers or academic careers at multiple institution types.
- Individualized, well supervised research experiences & career development guidance for scholars selected by the grantee institution
- Encouragement/expectation to subsequently apply for individual K awards (e.g. K08, K23, K01) or research project grants (R03/R21/foundation/R01)

Early Research Career Development

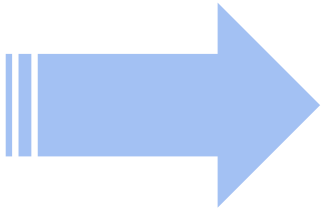


Scored Review Criteria

Candidate

<u>Important Proposal Docs</u>

- Biosketch
- Candidate's Background
- Career Goals & Objectives
- Letters of Reference

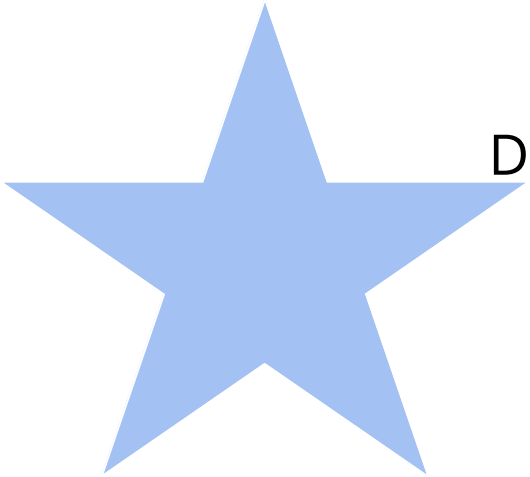


Independent Research Career

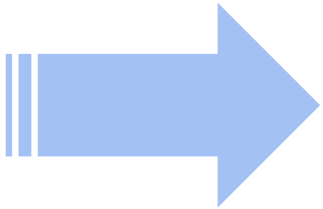
Scored Review Criteria

<u>Important Proposal Docs</u>

- Training Plan
- Mentor(s) Statement
- Advisory Committee letters



Career Development Plan



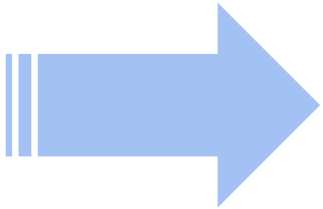
Independent Research Career

Scored Review Criteria

<u>Important Proposal Docs</u>

- Mentor(s) Statement
- Advisory Committee letters
- Mentor(s) & Advisors Biosketches

Mentors



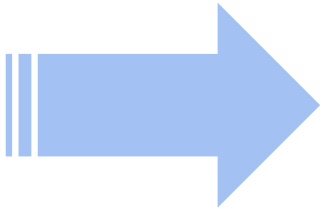
Independent Research Career

Scored Review Criteria

<u>Important Proposal Docs</u>

- Institutional Commitment letter (Dept Chair)
- Institutional Environment
- Facilities & Other Resources

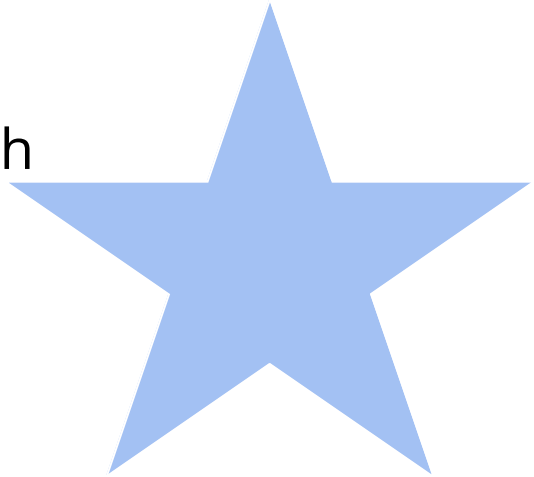
Environment & Institutional Commitment

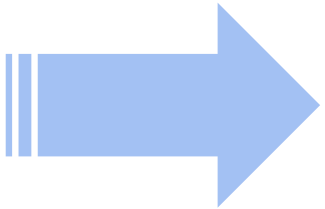


Independent Research Career

Scored Review Criteria

Research Plan





Independent Research Career

<u>Important Proposal Docs</u>

- Specific Aims
- Research Strategy
  - Significance
  - Innovation
  - Approach