### WELCOME!

# WHAT YOU NEED TO KNOW TO START AND COMPLETE AN EFFECTIVE K99/R00 APPLICATION NOV 11<sup>TH</sup>, 2020

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Biology & Medicine

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i Poll is full and no longer accepting responses

## Describe in one word how you are feeling at this point in your training



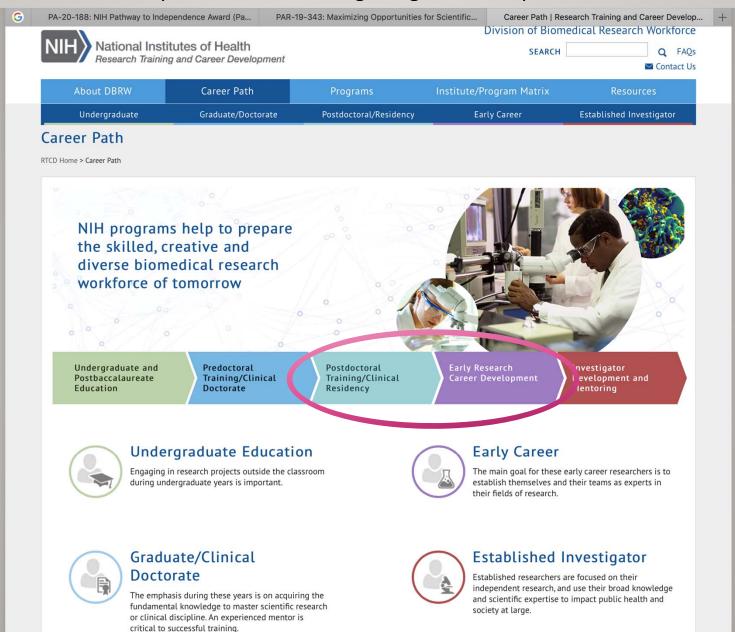


**Insert activity** 

## I. OVERVIEW OF THE K AWARD

II. GETTING STARTED
III. WRITING AN EFFECTIVE APPLICATION

### https://researchtraining.nih.gov/career-path



## **CAREER (K) KIOSK**

### HTTPS://RESEARCHTRAINING.NIH.GOV/PROGRAMS/FELLOWSHIPS

#### NIH Programs for Postdoctoral Researchers and Clinical Residents

#### You apply for Individual Awards:

F32

#### Ruth L. Kirschstein Postdoctoral Individual National Research Service Award

To provide postdoctoral research training to individuals to broaden their scientific background and extend their potential for research in specified health-related areas.

Details

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.

Details

K07

#### Academic Career Development Award

To support either a mentored or independent investigator to develop or enhance curricula, foster academic career development of promising young teacher-investigators, and to strengthen existing teaching programs.

Details

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.

Details

K22

#### Career Transition Award

To provide support to outstanding newly trained basic or clinical investigators to develop their independent research skills through a two phase program; an initial mentored research experience, followed by a period of independent research.

Details

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.

Details

K25

#### Mentored Quantitative Research Career Development Award

To support the career development of investigators with quantitative scientific and engineering backgrounds outside of biology or medicine who have made a commitment to focus their research endeavors on basic or clinical biomedical research.

Details

K43

#### **Emerging Global Leader Award**

To provide research support and protected time to a junior scientist with a faculty position at an LMIC institution leading to an independently funded research career.

Details

K76

#### **Emerging Leaders Career Development Award**

To advance the development of physician-scientists prepared to take an active role in addressing present and future challenges of a global biomedical research enterprise.

Details

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.

Details

You apply for Loan Repayment Programs:

## CLINICAL TRIALS IN K AWARDS

\*Be sure to look at the correct Funding Opportunity
Announcement (FOA) to see if independent clinical trials
permitted

## Independent Clinical Trial

- Led and funded by the PI of the K application
- May be an independent ancillary trial to a larger trial or a feasibility study.
- Human subjects/clinical trial form required

## Clinical Trials Research Experience

K applicant participates in a clinical trial led/funded by a mentor

## WHAT IS K99/R00 ALL ABOUT?

### **Program Purpose**

- Facilitate a timely transition from postdoc to independent, tenure-track or equivalent faculty positions
- Mentored phase (K99) provides 1-2 years of mentored support to promising postdoc (up to \$100K/yr)
- Followed by up to 3 years of independent support (R00)
   contingent on independent research position (up to \$249K/yr),
   apply for R01.
- If an applicant achieves independence before a K99 award is made, neither the K99, nor the R00 award, will be made.

## WHO IS ELIGIBLE?

- U.S. citizen/non-citizen, with research or clinical doctoral degree (PhD, MD, DO, DC, ND, DDS, DMD, DVM, ScD, DNS, PharmD)
- No more than 4 years of Postdoc research experience @ application (Possible exceptions for parental, medical, other leave, or non-research residency training)
- Institution must be US Domestic Institution
- For non-U.S. citizens with temporary U.S. visas, visa status during each phase of the K99/R00 award must allow the PD/PI to conduct the proposed research at the applicant institution.



Program Officer to confirm eligibility (PA lists participating institutes)

## MOSAIC AWARD

- Facilitate a timely transition from postdocs from diverse backgrounds to independent, tenure-track or equivalent faculty positions in research-intensive institutions
- Offered through NIGMS
- Paired with UE5 which funds independent organizations to support educational activities to provide cohorts of MOSAIC K99/R00 scholars professional skills training, mentoring, and professional networking
- Enhance institutional accountability for the scholars' career advancement
- \*\*By the time of award, the individual must be a citizen or a non-citizen national of the United States or have been lawfully admitted for permanent residence

## BEFORE GETTING STARTED

- ✓ Assess your career situation and needs...
- ✓ Is the K99/R00 the right award for you, or would another award be more appropriate?
- ✓ Take a deep breath, this process will benefit you regardless of whether you are funded!



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II. GETTING STARTED

III. WRITING AN EFFECTIVE APPLICATION

## **TIMELINE FOR K APPLICATIONS**









**Receipt Date:** 

**Review**:

**Council:** 

**Award Date:** 

• Feb 12 (Mar 12)

Jun/July

October

December

■ Jun 12 (Jul 12)

Oct/Nov

January

April

Oct 12 (Nov 12)

■ Feb/Mar

May

■ Ju**§** 

\*Start at least 6 months prior to the application

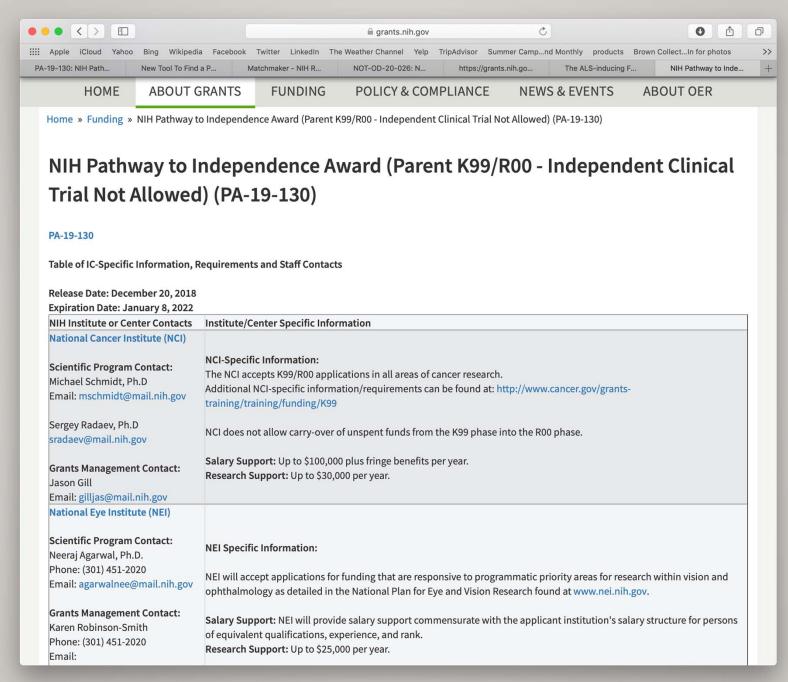
\*Aim for complete draft at least 1 month before due date



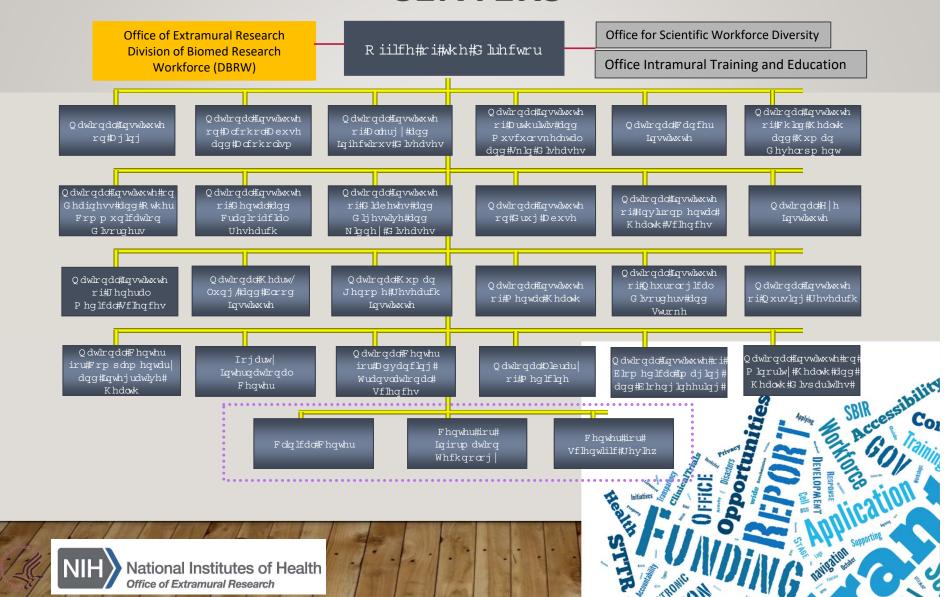
## \*\*BECOME FAMILIAR WITH PARENT ANNOUNCEMENT\*\*

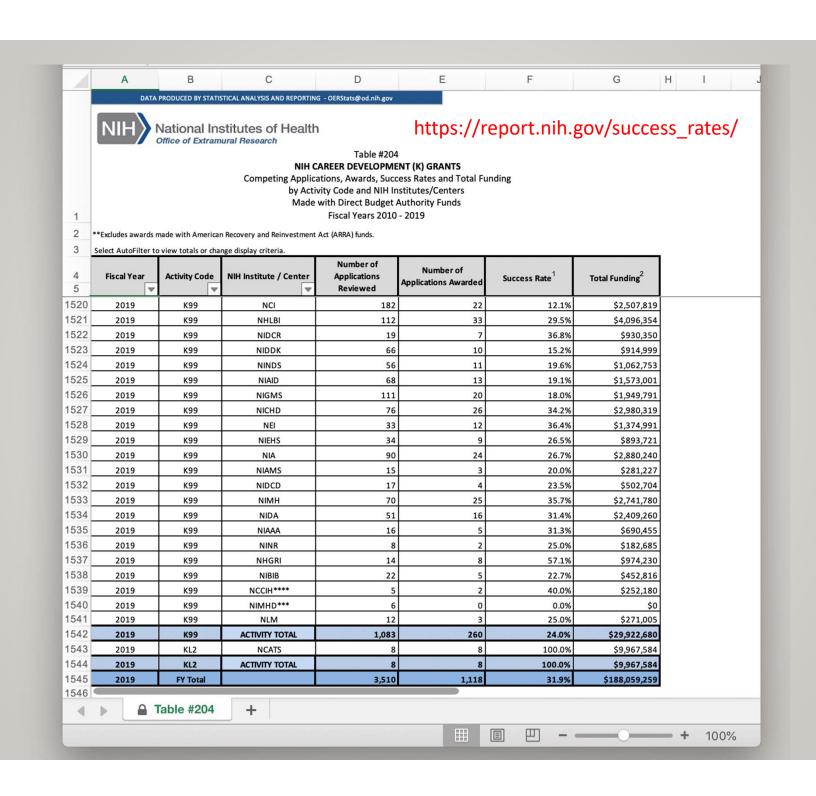
https://grants.nih.gov/grants/guide/pa-files/PA-19-130.html

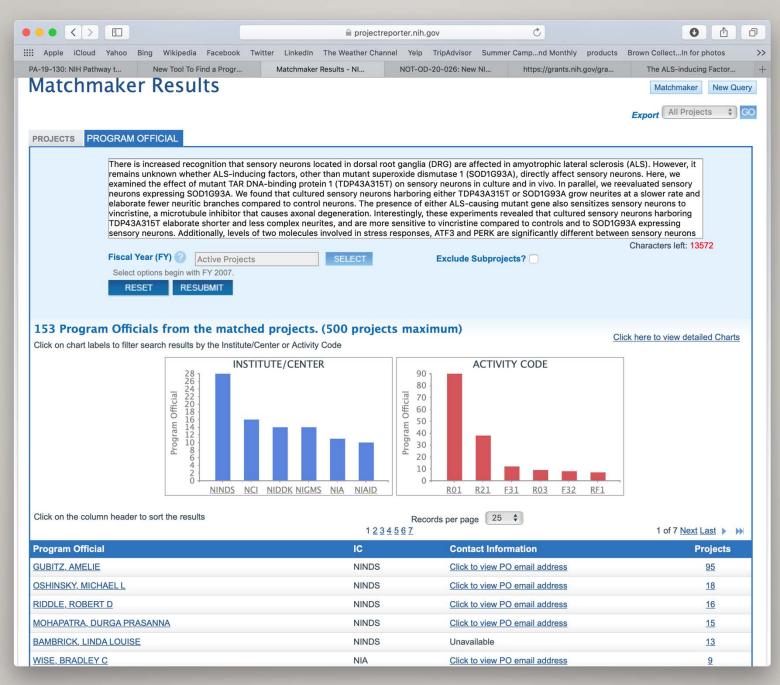
PA-20-130: NIH Pathway to Independence Award (Parent K99/R00 - Independent Clinical Trial Not Allowed)
PAR-19-343: Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Postdoctoral Career Transition Award to Promote Diversity (K99/R00 - Independent Clinical Trial Not Allowed)



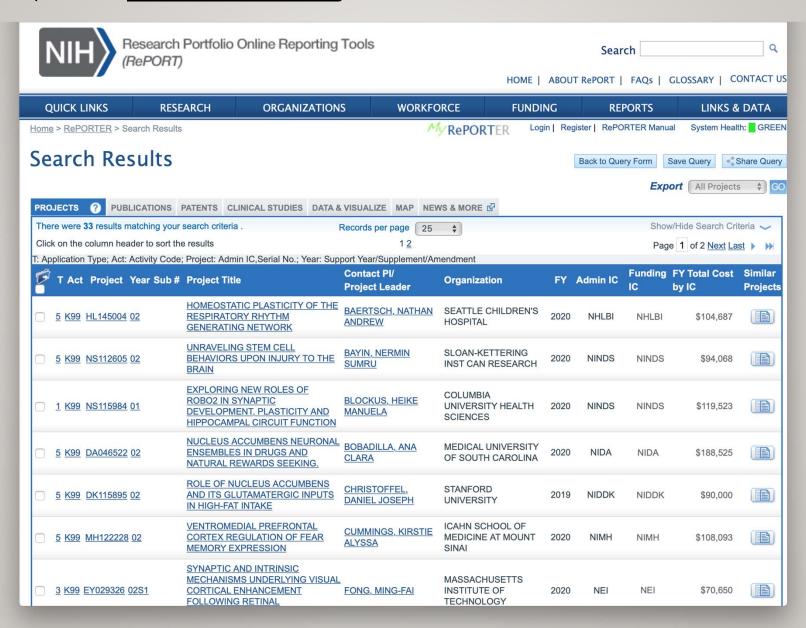
## NIH INCLUDES 27 INSTITUTES AND CENTERS

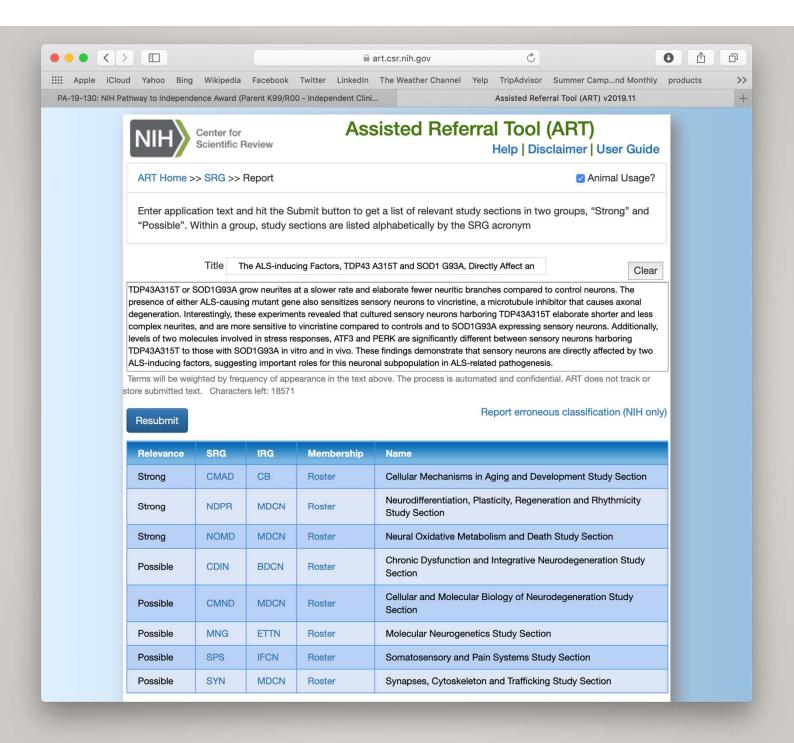


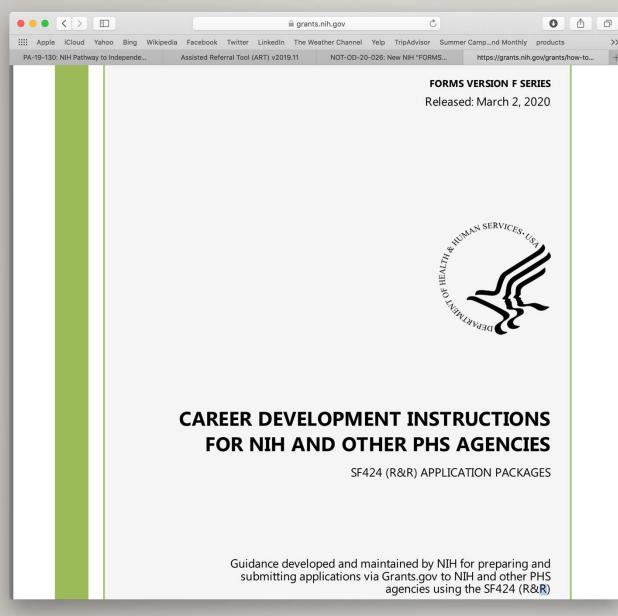




## See what is being funded by NIH: Research Portfolio Online Reporting Tools (RePORT: <a href="https://report.nih.gov">https://report.nih.gov</a>)







- 1. Contact your department's grant specialist (Authorized Organizational Representative) to assist with the application
- Download the application instructions
- 3. Get an NIH Commons Account

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/career-forms-f.pdf

### NIH Career Development Checklist - Forms E

Ц	Cover Letter (required for Mentored Career Development, generally 1 – 2 pages)
	Project Summary/Abstract (30 lines of text maximum)
	Project Narrative (2 or 3 sentences maximum)
	Bibliography & References Cited
	Facilities & Other Resources
	Equipment
	Biographical Sketches – applicant and mentor/co-mentor(s) (5 page limit)
	Current and Pending Support (mentor/co-mentor(s) only, 3 page limit for each)
	Budget Justification
	Introduction to Application (for resubmission only, 1 page limit)
	Candidate Information and Goals for Career Development
	Specific Aims (1 page limit)
G	Research Strategy (12 page limit for both Research Strategy and Candidate Information and bals for Career Development combined)
	Progress Report Publication List (renewal applications only – not applicable for career awards)
	Training in Responsible Conduct of Research (1 page limit)
	Plans and Statements of Mentor and Co-Mentor(s) (6 page limit)
	Letters of Support from Collaborators, Contributors, and Consultants (6 page limit)
	Description of Institutional Environment (1 page limit)
	Institutional Commitment to Candidate's Research Career Development (1 page limit)
	Protection of Human Subjects (if human subjects involved)
	Data Safety Monitoring Plan (if clinical trial)
	Inclusion of Women and Minorities (if human subjects involved)
	Inclusion of Children (if human subjects involved)
	Vertebrate Animals (if vertebrate animals used)
	Select Agent Research (if application involves the use of select agents)
	Resource Sharing Plan
	Authentication of Key Biological and/or Chemical Resources (1 page limit)
	Appendix
	Inclusion Enrollment Report
	Assignment Request Form
	Reference Letters (submitted via eRA Commons)

#### K01/K07/K08/K18/K22/K23/K25/K43/K76/K99-R00 Review

Application #:

Strengths Weaknesses

Principal Investigator(s):

#### OVERALL IMPACT

Reviewers will provide an overall impact score to reflect their assessment of the likelihood that the proposed career development and research plan will enhance the candidate's potential for a productive, independent scientific research career in a health-related field, taking into in consideration of the following five scored review criteria, and additional review criteria. An application does not need to be strong in all categories to have a major impact.

Overall Impact Write a paragraph summarizing the factors that informed your Overall Impact score.

#### SCORED REVIEW CRITERIA

Reviewers will consider each of the five review criteria below in the determination of the candidate's qualifications, scientific and technical merit of the proposed research, career development plan, mentor's qualifications and mentoring plan, environment and institutional commitment to the candidate, and give a separate score for each.

1. Candidate	
Strengths	
Weaknesses	
Career Development Plan/Career Goals & Objectives	
Strengths	
Weaknesses	
3. Research Plan	
Strengths	
Weaknesses	
4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)	
Strengths	
Weaknesses	
5. Environment and Institutional Commitment to the Candidate	

#### ADDITIONAL REVIEW CRITERIA

As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit, but will not give separate scores for these items.

- X A response for Protections for Human Subjects, Vertebrate Animals, and Biohazards is required from reviewers for all applications.
- X A response for Inclusion of Women, Minorities and Children is required from reviewers for Human Subjects Research Applications.

Study Timeline (Specific to applications designated clinical trial on the electronic cover sheet)

#### Strengths

NA

#### Weaknesses

NA

Protections for Human Subjects

Acceptable Risks and Adequate Protections

Comments (Required Unless Not Applicable):

.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

Comments (Required Unless Not Applicable):

Included but not required and flawed in detail provided.

Inclusion of Women, Minorities and Children Applicable Only for Human Subjects research and not IRB Exemption #4.

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- · For NIH-Defined Phase III trials, Plans for valid design and analysis: Not applicable
- Inclusion/Exclusion of Children under 18: Excluding ages <18; not justified scientifically</li>

Comments (Required Unless Not Applicable):

The justification for not including children is inadequate based on NIH policy.

## **DEVELOP A STRATEGY**

- Identify mentor(s) and collaborators- discuss your project and career development needs, be sure they are on board
- Be sure your proposed project is distinct from your mentor's research and that the mentor is supportive of future independence
- Identify and notify referees to write reference letters
- Consider your strengths and areas for growth- do the individuals and training opportunities you have in mind complement your strengths and fuel this growth [why is the K appropriate?]

## **IDENTIFY INSTITUTIONAL RESOURCES**

Your Institution's OVPR/OSP website

Example: Go to the Brown BMRA website, under the GUIDANCE

tab <a href="https://www.brown.edu/academics/biomed/offices-and-services/research-administration/guidance">https://www.brown.edu/academics/biomed/offices-and-services/research-administration/guidance</a>

Your Institution/Department/Center's grant resources

Example: Scroll down the table and you will find "Research Resources" for <u>Brown</u>, <u>Care New England</u>, <u>CORES</u>

RI, <u>Lifespan</u>, <u>University of Rhode Island</u>, and the <u>VA</u>.

## I. OVERVIEW OF THE K AWARD II. GETTING STARTED

III. WRITING AN EFFECTIVE APPLICATION

## **KEY APPLICATION COMPONENTS**

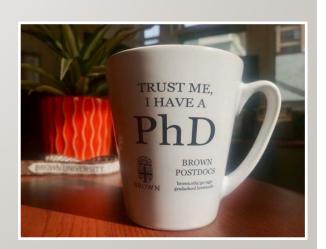
- Biosketch; Candidate Information and Goals for Career Development
- Plans and Statements of Mentor and Co-Mentors;
   Biosketches
- Institutional Environment & Commitment to the Candidate's Research and Career Development
- Specific Aims & Research Strategy

## **BIOSKETCH HIGHLIGHTS**

- Personal statement highlight relevant research experience and other qualifications for this K award
- Contributions to science emphasize research
   publications or research products related to the K award
- Research support ongoing and completed research projects
- Emphasize any existing collaboration with mentor(s)/collaborators

## CANDIDATE INFORMATION

- Highlight important aspects of your career trajectory and commitment to an academic research career
- Research achievements, experience, and potential to successfully transition to independence
- Other relevant experience (leadership, teaching, mentoring)
- Collaborations (supported in letters)
- It is ok to repeat content from your Biosketch



## CAREER GOALS AND OBJECTIVES, PLAN FOR CAREER DEVELOPMENT

- Explain what new research skills and enhanced knowledge you will gain. How does this fit with overall career goals and research direction?
- Identify other mechanisms for professional development (for-credit courses, workshops, conferences, networking)
- Include details of mentorship plan (duration and frequency of meetings)
- Provide a timeline for implementing career development plan (including future publications and awards)
- It should be clear how these goals align with your research strategy, and why mentored (K99) phase is needed

## EXAMPLES (AVAILABLE ON NIH WEBSITE)

Timeline of Career Development Activities (percent effort/year where applicable)										
Training Activity	Year 1		Year 2		Year 3		Year 4		Year 5	
Workshops	2									
AAI Immunology Seminar/ CSHL Stats Methods Genomics	(2)			(2)						
Bioinformatics & Computational Biology Courses										
Fundamentals of Epidemiology/Advanced Epidemiology	(10)	(10)								
Linear Regression/Categorical Data Analysis			(10)	(10)						
Computational Systems Biology/Biostatistics Computing					(10)	(10)				
Next Gen Genomic Data Analytics/Biological Database Mgmt							(10)	(10)		
Machine Learning for Bioinformatics									(10)	
Coursera Systems Biology Specialization (on-line)	(2)	(2)	(2)	(2)	(2)					
Conduct of research and ethics										
Introduction to Research Ethics course (GRAD G504)	(10)									
Responsible Conduct of Research and CITI renewals										
Grantsmanship and career development										
Grant Writer's Workshop & Scientific Writing Course										
Conference Attendance										
American Society of Tropical Medicine & Hygiene										
Gordon Research Conference/Keystone Symposium										

## EXAMPLES (AVAILABLE ON NIH WEBSITE)

Meeting/Group	Frequency (Duration)	Description and Goals					
Mentor meeting: Dr. Sterling	Weekly (60 minutes)	Individual meetings with mentor, co-mentor, and mentoring committees to guide and assess progress toward career					
Co-Mentor meeting: Dr. Graves	Bi-Weekly (60 minutes)	development, educational, and research goals. Includes intensive discussion and feedback from senior faculty and elite researchers					
Internal Advisory Committee: Drs. Schaffner, Fonnesbeck, and Shepherd	Quarterly (90 minutes)	in health policy, epidemiology, and biostatistics at both Vanderbilt (internal advisory committee) and Johns Hopkins (external advisory committee). Meetings with faculty at JHU will be held via					
External Advisory Committee: Drs. Holtgrave and Gange	Semi-Annual (90 minutes)	teleconference/videoconference, except for semi-annual visits to Baltimore, MD.					
Policy meetings: Dr. Cheever, Administrator of HRSA HIV/AIDS Bureau (and HRSA partners)	Quarterly (90 minutes)	In-person/teleconference meeting with federal policy makers with implementation of evidence-based policy specific to vulnerable HIV populations in their purview; will focus on practical implications and priorities of research for policy/programmatic changes.					
Epidemiology/Outcomes Group (Vanderbilt)	Weekly (60 minutes)	Dr. Sterling leads this meeting of data abstractors, data managers, biostatisticians (including Dr. Shepherd), and epidemiologists involving discussion of ongoing research using the Vanderbilt Comprehensive Care Clinic cohort, and collaborations with various outside groups (e.g., NA-ACCORD, CCASAnet, TN DOH, et al.).					
Health Policy Methodology (Vanderbilt) (continued)	Monthly (90 minutes)	Dr. Graves leads this meeting of health policy analysts, epidemiologists, and biostatisticians to explore solutions to methodologic issues in the use of epidemiologic cohort data to answer policy-oriented questions. As cohort data may not allow inference to the appropriate policy-impacted target population, weighting or calibration techniques may be developed to derive externally valid inferences.					
NA-ACCORD	Monthly	Drs. Moore and Gange lead this meeting of data managers, analysts, investigators, epidemiologists, and coordinators of NA-					

## EXAMPLES (AVAILABLE ON NIH WEBSITE)

Table 1. Mentoring Committee									
Name Associated (Institution) Aims/Goals*		Meeting Frequency and Format	Area of Expertise and Role						
Samir Shah, MD, MSCE (CCHMC, UC) [Primary Mentor]	Research: 1,2,3 Training:1, 3, 4	Weekly meetings (and informally as needed, in person)	Expertise: Pediatric community-acquired pneumonia, infectious diseases, hospital medicine, clinical epidemiology, multicenter inpatient studies (Vice Chair of the PRIS Network), leadership skills Role: Primary mentor for pneumonia, career guidance, study design and execution, multicenter research						
Maurizio Macaluso, MD, DrPH (CCHMC, UC) [Co-Mentor]	Research:1,2,3 Training:3,4	Monthly (in person)	Expertise: Advanced epidemiological methods, causal inference, molecular epidemiology  Role: Career mentor, primary mentor for molecular epidemiology						
Kathleen Stringer,	Research: 1,2,3 Training:1, 3, 4	Every other week (by phone/Skype), in person at 3x/year	<b>Expertise:</b> quantitative NMR metabolomics, metabolomics study design and execution using biofluids including urine, statistical and						

	idation of the L	tiology of Pneumonia	Lilliam Ambroggio, PhD, MPH					
PharmD			bioinformatics analysis aimed at identifying metabolites of biological					
(UMichigan)			relevance, inflammatory lung diseases					
			<b>Role:</b> Primary mentor for metabolomics, onsite externship at University of Michigan (3 2-week visits in year 1)					
Richard Ruddy, MD (CCHMC, UC)	Research: 1,2,3 Training: 1, 4	Monthly (in person)	<b>Expertise:</b> Multicenter pediatric emergency medicine research (nodal P for PECARN), respiratory diseases in ED, leadership skills, <b>Role:</b> Content expertise for pediatric emergency medicine research, career guidance					
Heidi Sucharew.	Research:	Monthly (year 1 and 5, in	<b>Expertise:</b> Cluster analysis, functional data analysis with extension to					
PhD	1.2.3	person)	large scale data such as metabolomics, latent class models					
(CCHMC, UC)	Training: 2	Every other week (years 2-4, in person)	Role: Statistical mentor on analysis of metabolomics dataset					
Additional Collab	orators (not on M	lentoring Committee)						
Lindsey Romick- Rosendale, PhD	Research:1,2,3 Training:1	Every other week (Years 1-3, in person); Monthly	Expertise: 6 years of NMR metabolomics experience, complex metabolic pathways involved in diseases/infections					
		with Dr. Stringer (Year 1-3); Monthly (Year 4-5)	Role: CCHMC onsite metabolomics expert, guidance in study design, execution and interpretation of NMR metabolomics portion of the proposal					
Assem Ziady, PhD	Research:1,2,3 Training:3	Monthly (Year 4-5, in person)	Expertise: Proteomic and metabolomics study studies using Liquid Chromatography Mass Spectrometry (LC/MS), inflammatory signaling in children with cystic fibrosis					

## MENTOR(S), COLLABORATOR(S), CONSULTANT(S)

### Primary Mentor(s) must:

- Explain how they will contribute to your development
- Demonstrate commitment to meeting with you regularly, coordinating with mentorship team, annual assessment of progress
- Document sufficient independent research support to cover your project during the K99 phase
- Discuss the plans for transitioning you to independence by the end of the K award, including support during job search
- Provide details of research qualifications and previous experience as a mentor (including outcomes of mentees)

## INSTITUTIONAL ENVIRONMENT & STATEMENT OF INSTITUTIONAL COMMITMENT

- Document a strong, well-established research and career development program related to the candidate's interests
- Experienced faculty, facilities and resources
- Opportunities for intellectual interactions, e.g., journal clubs, seminars, and presentations
- Commitment to the candidate's career development independent of the K award
- Adequate office and lab space, time (75% effort)
  and support to the candidate for the period of K
  award
- Availability of appropriate time and support for mentors, consistent with what has been proposed



## SPECIFIC AIMS OF THE PROJECT

- State the problem or barrier to progress, why you can solve it, what's novel
- Avoid interdependent aims
- State hypothesis related to each aim, be sure it is testable with the time and resources you have for the award period
- May include a summary figure
- Last few sentences should concisely explain how this work will make a major contribution to the field, and how the research and training will impact your career development

## **RESEARCH STRATEGY**

- Must span both phases of the K99/R00 award
- Say what you will accomplish during the mentored phase research that will enable you to launch an independent research program





## **RESEARCH STRATEGY**

### Significance:

- The importance of the problem you are trying to solve
- How existing concepts, methods, tools, technologies, treatments, or interventions may be impacted if the proposed aims are achieved

### **Innovation:**

- How your proposed research will challenge or improve current research or clinical practice paradigms
- Novel theoretical concepts, approaches, methodologies, or interventions that may be developed or used

## **RESEARCH STRATEGY**

## Approach:

- Methods and analyses to test the hypotheses and accomplish the specific aims (attention to positive and negative controls or randomization where appropriate).
- Benchmarks for success anticipated to achieve the aims.
- Potential pitfalls and alternative strategies.
- Feasibility with the time and resources you have
- Rigorous experimental design power calculations, sufficient N, biological variables, appropriate statistical tests and authentication of reagents.

## **EXAMPLES**

Requested start date: July 2017	2017 (Year 1)	2018 (Year 2)	2019 (Year 3)	2020 (Year 4)	2021 (Year 5)	
Preparatory to Research						
Acquire concept sheet and IRB approvals from all groups						
Aim 1		na v sav u va	7			
Clean & aggregate data; perform longitudinal analyses						
Abstract submission (Fall, 2018)						
Internal peer-review and manuscript submission/revision						
Perform spatial analyses and map adjusted outcomes						
Internal peer-review and manuscript submission/revision						
Aim 2						
Clean data; perform difference-in-difference analyses						
Abstract submission (Fall, 2019)						
Internal peer-review and manuscript submission/revision						
Aim 3						
Clean data; perform difference-in-difference analyses						
Abstract submission (Fall, 2020)						
Internal peer-review and manuscript submission/revision						
Additional analyses, agent-based models, & publications						
R-01 grant writing/submission						
Initial submission in Sept. 2019 (allows for resubmission)						

## **SOME FINAL POINTERS**

- Work on writing concisely (challenging page limits)
- Use graphics and figures, but must be readable
- Involve mentors and colleagues in editing/proofreading process
- Do not be overambitious, proposed work should be realistic
- Remember: all components must be coordinated to make a case for why this award will benefit your career and transition to independence

## QUESTIONS?