



FROM CONCEPT TO SUBMISSION: HOW TO MENTOR GRANT WRITING

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Types of Mentored Career Development Awards

- There are a number of different mentored K awards that individuals with a research or health professional doctorate should consider.
- Most of these awards support individuals *after* they have completed training and are transitioning to a faculty position.

Key Features of Mentored K Awards

- 3 – 5 years in length
- Provide substantial salary support but limited research funding.
- Contain both a training plan *and* a research plan.
- Includes a team of mentors, co-mentors, advisors, etc.
- Goal: transition to research “independence”.

Types of Mentored Career Development Awards (cont'd)

- **K08: Mentored Clinical Scientist Research Career Development Award:**
 - ▣ Development of the independent clinical research scientist
 - ▣ Mainly for MDs planning basic science research career— not patient-oriented research
- **K23: Mentored Patient-Oriented Research Career Development Award:**
 - ▣ Development of the independent research scientist in a clinical arena
 - ▣ Clinician interacting directly with patients for your research
 - ▣ By the time of award, the PD/PI (Career Candidate) must be a U.S. citizen or permanent resident, must have a health-professional doctoral degree, and must have completed their clinical training and specialty training.

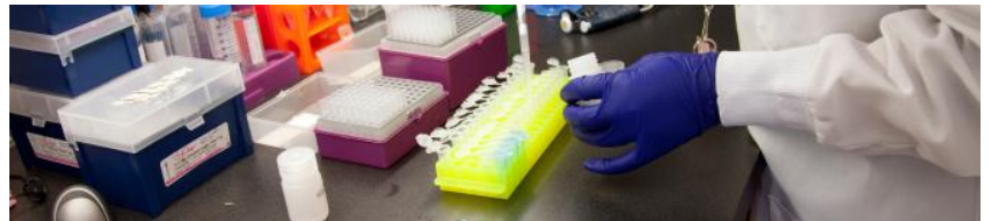
Types of Mentored Career Development Awards (cont'd)

■ K12: Mentored Clinical Scientist Development Program Award:

- Support for an institution for the development of independent clinical scientists in a certain field

BIRC_WH Building Interdisciplinary Research
Careers in Women's Health

NIH Diversity Awards



Women's Reproductive Health Research (WRHR)

CTSI K Scholar Program Call for Applications

Other Types of NIH Mentored Career Development Awards

- **K99/R00: NIH Pathway to Independence (PI) Award:**
 - ▣ Provides an opportunity for promising *post-doctoral* scientists to receive both mentored and independent research support from the same award.
 - ▣ Can be resident (need not be US citizen)
 - ▣ The PD/PI (Career Candidate) must have a research or health professional doctoral degree, with no more than 4 years of postdoctoral research experience at the time of the initial or the subsequent resubmission or revision application.
 - ▣ Kangaroo award

General Tips on Mentored K Awards

- Understand the *intent* of the mentored K award.
 - ▣ To help promising new investigators achieve research independence (i.e., to compete successfully for *R01 funding*).
 - ▣ Therefore, preparing for the R01 grant application you will submit at the end of the K award should be the *organizing principle* of the K grant application.

General Tips on Mentored K Awards (cont'd)

- Make a compelling argument why you need a K award
 - ▣ Explain exactly how additional training and mentored research experience will enable you to compete successfully for R01 funding.
 - ▣ Be specific: give concrete examples of areas where you need additional training or experience in order to conduct the proposed research or areas where you are deficient that are directly related to your research career goals.

General Tips on Mentored K Awards (cont'd)

- Develop a career development training plan that is *uniquely* suited to you.
 - ▣ Given your previous training and research experience, and your short- and long-term career goals, propose a mix of didactic training and “hands- on” research experience that make perfect sense for you (and only you).
 - ▣ Degree-granting programs (e.g., MPH, MAS) are appropriate for candidates with little or no previous formal training in research, but even these programs should be “customized” whenever possible.

6. Research plan

□ **General format:**

- Significance aims page (1)
- Significance
- Innovation
- Approach
 - Preliminary Studies
 - Research design and methods
- (Protection of Human Subjects, Inclusion of Women and Minorities, Inclusion of Children)
- References (unlimited)

More tips

- **The unit of currency as you apply is publications**
 - ▣ This isn't changing
 - ▣ No new currency in the works
 - ▣ Try to have a theme built up in your publications (“developing a niche”)
 - ▣ Try not to have the same mentor as last author every time (“beginning of independence”)
 - ▣ Few quality publications (higher impact journals, solid demonstration of an important finding) better than quantity



Tips

- **Start early on your application and clear decks**
 - Try to give *at least* 3 months
 - Contact your RSA early to get a timeline of when documents are due
 - Cancel standing meetings, don't meet with students, clear clinical obligations, only keep necessary balls in air
 - Work in your best location (holed up, café, library, etc.)
 - Identify your 3-4 internal reviewers early (NOT MORE), email them ahead of time with stated commitment of when draft will arrive and when you need comments
 - Look at study section roster of your intended study section – ***use their references if possible***

Tips

□ Grantsmanship means a lot

- Don't crowd page with words, have white space, clear language
- Use indentations, boxes (pull-out with key points)
- Can use some color- box your aims, color figures/tables
- Use Figures/Tables that are clean, easy to read
- Bold key points (not too much)
- Don't start with "HIV affects 38.4 million people worldwide"
– reviewers know that, hone in on your problem
- Don't hit reviewer over head with preliminary studies or summarizing literature- key points and heavily use references
- Tell a story of innovation

research priority for wide-scale HIV biomedical prevention trials and implementation efforts.⁵⁰

3A2a. Examples from HIV prevention trials where low adherence may have “flattened” results, over-reporting of adherence was common, and an objective biomarker of adherence proved it: Recent data from HIV prevention trials have demonstrated that traditionally-used measures of adherence perform poorly, highlighting the importance of biomarkers of adherence. **Table 1** summarizes recent examples from HIV prevention trials where adherence was over-reported using “traditional” measures such as self-report or pill counts, compared to data from more objective markers.^{1,33,35,53} **The iPrEx trial provides an example where low adherence to study product blunted efficacy estimates considerably.**¹ In this trial, although mean adherence by self-report or pill counts was 95% in the group assigned TFV/FTC, adherence assessed by drug detection in peripheral blood mononuclear cells (PBMCs) was found to be only 8% in those who seroconverted and 54% in those who remained uninfected.

Table 1: HIV Prevention RCTs where Including Objective Biomarkers of Adherence Radically Changed Outcomes

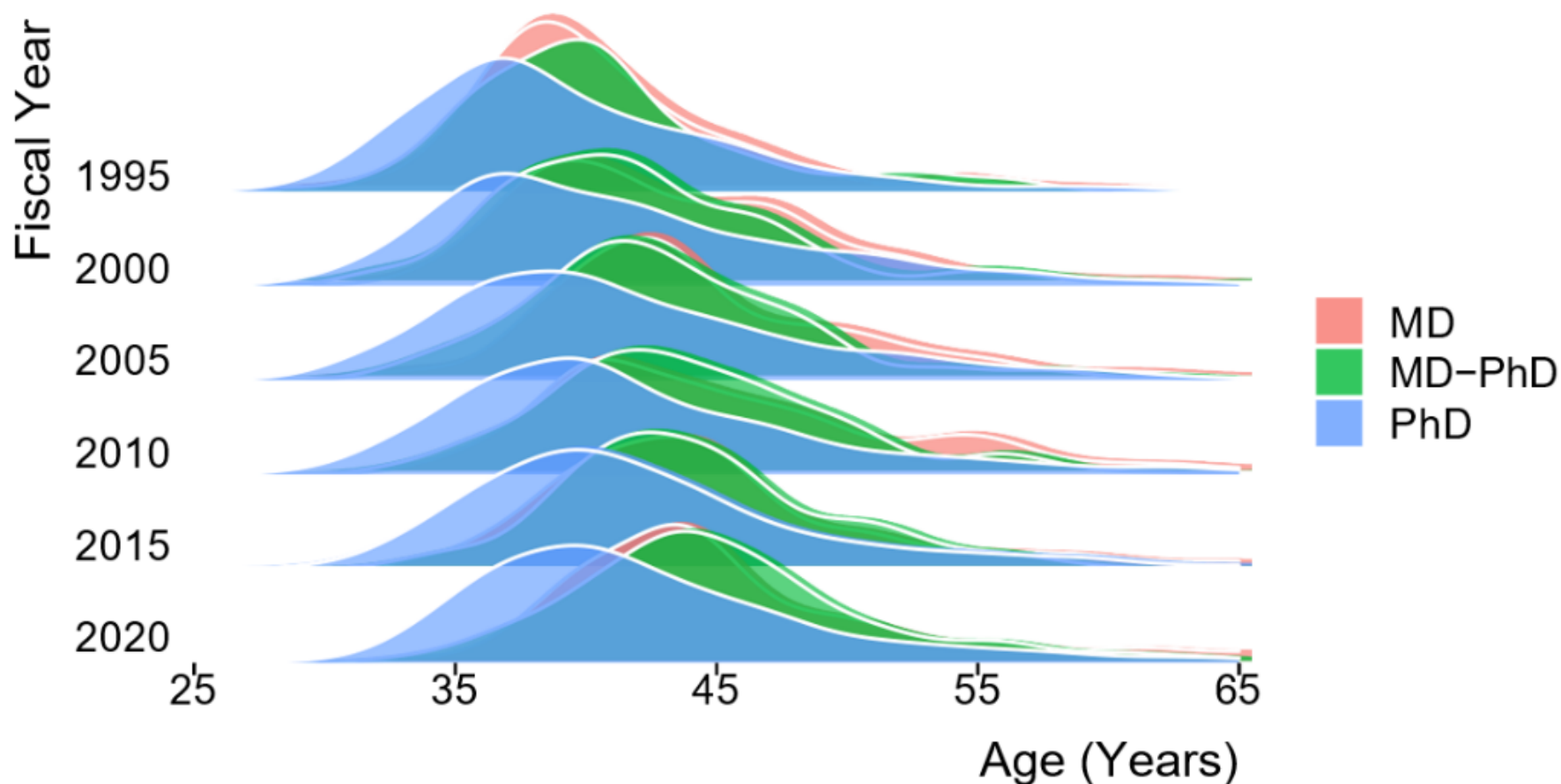
Trial	Reference	Adherence as assessed by “traditional measure” in active arm	Adherence as assessed by objective biomarker	Likely effect of low adherence to product	Limitations of objective biomarker used (Table 2)
Global iPrEx (oral PrEP, MSM)	Grant. NEJM 2010 ¹	89-95% by self-report or pill-counts	<50% by PMBC data (8% adherence or drug detectable in those who seroconverted; 54% in those who did not)	“Blunted” efficacy results (from 92% to 44%)	PBMCs expensive, cumbersome to collect; plasma levels reflect only recent use
MTN-001 study (vaginal and oral PrEP, women)	Hendrix. CROI 2011 ⁵⁹	94% by self-report	35-65% by PK measures (PBMC, vaginal tissue concentrations)	NA (phase II, not an efficacy trial)	PBMCs expensive, cumbersome
Carraguard microbicide (vaginal gel, women)	Skoler-Karppoff. Lancet 2008 ⁴⁴	96.2% by self-report	41.1% by applicator testing (staining assay to see if applicators had been vaginally inserted)	No efficacy demonstrated	Staining assay complicated and relies on return of applicators
Acyclovir for HSV to prevent HIV (female HSV-2+ workers)	Watson-Jones. NEJM 2008 ⁴²	90% by self-report or pill counts	33-67% by testing of urine samples for acyclovir detection	No efficacy demonstrated	Urine difficult to collect and store (higher volumes)
FEM-PrEP (oral PrEP, women)	4/18/11- FHI Statement ¹²	95% by self-report or pill counts	Analyses of plasma ARV levels underway	To be determined	Pills subject to decanting before counts; plasma levels only recent use

Non-human primate data demonstrate very high efficacy of daily TFV/FTC for PrEP.^{58,59} Low adherence to study product in human trials of PrEP will obviously flatten efficacy results. The FEM-PrEP RCT, designed to assess the efficacy of TFV/FTC in African women for PrEP, was terminated early (on April 18, 2011) after interim analysis showed equal rates of infection in each group.⁵ **Although data are not yet available on the reasons for these interim FEM-PrEP results, nullification of efficacy by low adherence to study product is hypothesized and under investigation.** Indeed, high rates of pregnancy in those self-reporting oral contraceptive methods in FEM-PrEP allude to possible adherence limitations in the trial. Finally, a recent presentation from MTN-001, a large multinational phase II pharmacokinetics and

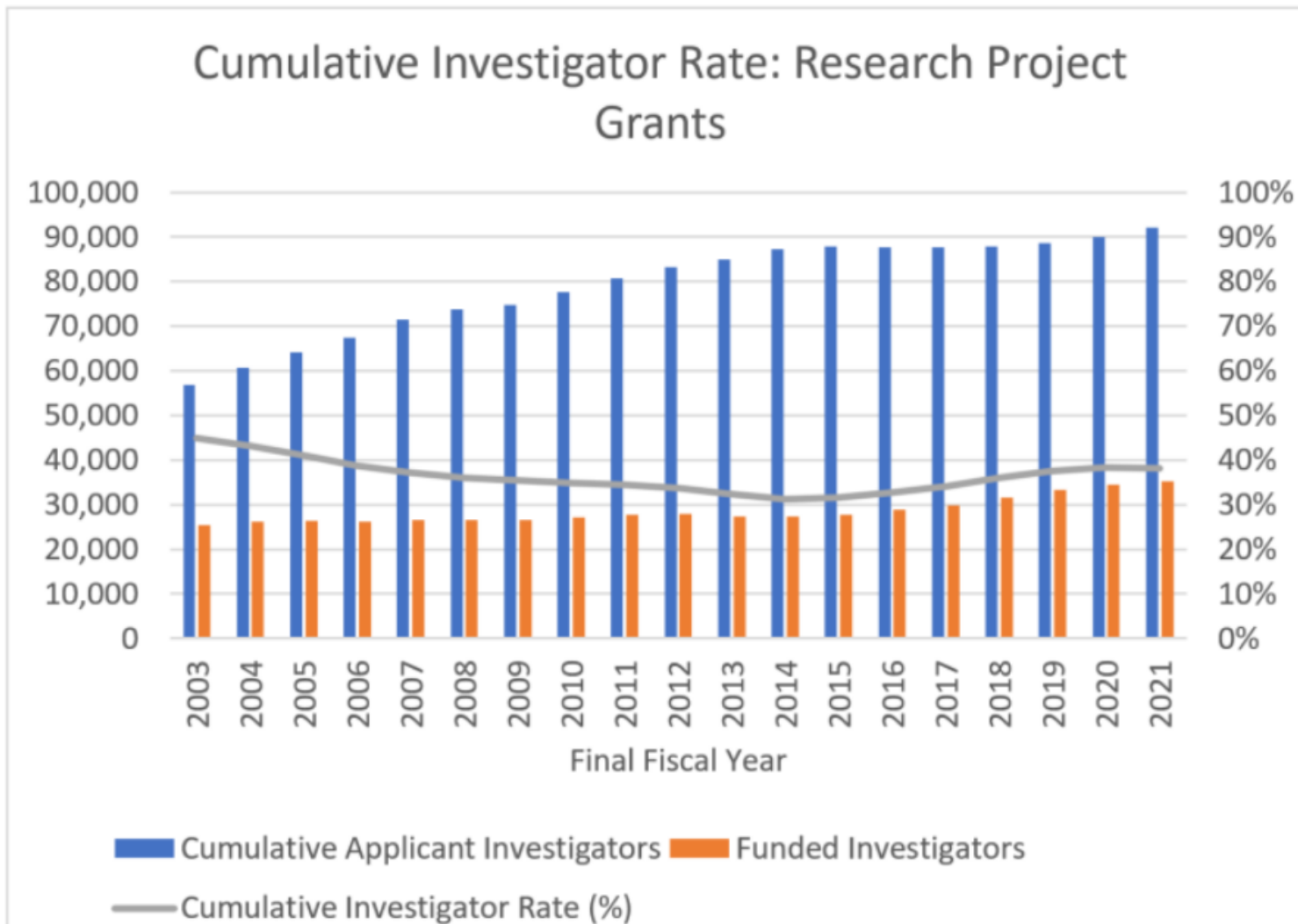
If you are not awarded the first time...

- Like in a manuscript review, if you are **very responsive, point-by-point**, HIGH CHANCES of getting funded the next time
- Ask the program officer for hints (may have been in review, will know program priorities for funding)
- Frame respectful point-by-point addressing of each question raised by the review
- Try to resubmit to same study section; going new may not help and at least you are responding to comments

Degree-based distributions by fiscal year of age of PI receiving support on NIH R01 for first time – November 2021

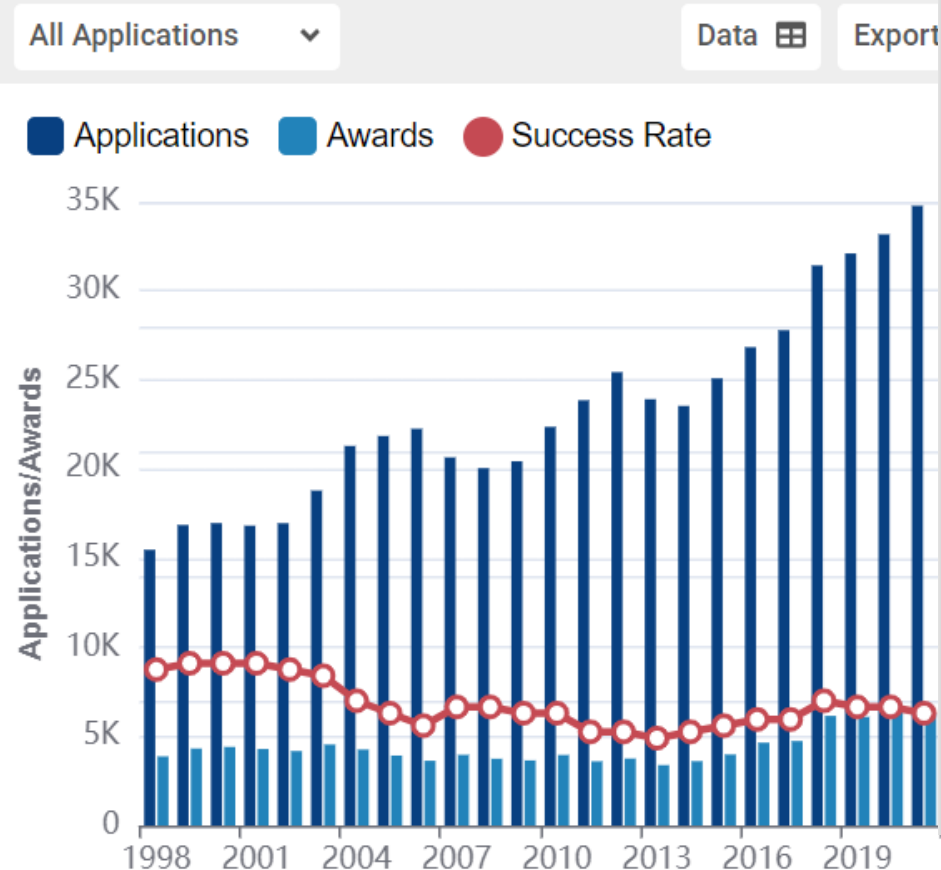


Number of applications going up to NIH- now at 38.2% funding rate



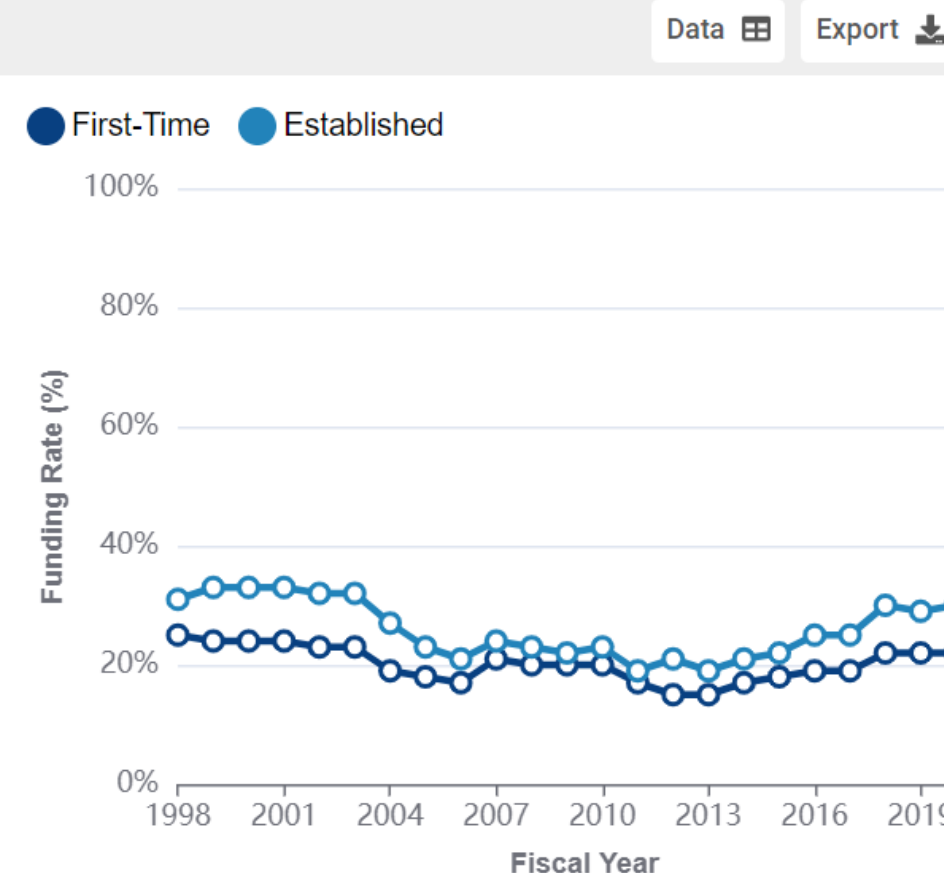
R01-Equivalent Grants, New (Type 1): Competing Applications, Awards, and Success Rates, by Career Stage of Investigator

NIH Data Book Report ID: 136 [Share](#)



R01-Equivalent Investigators, New (Type 1): Funding Rates, by Career Stage of Investigator

NIH Data Book Report ID: 166 [Share](#)



However, NIH encouraging early investigators

- 18% success rate for RO1s (new investigators) in 2021
- **Early Stage Investigator** program initiated 2009 (you have to be within 10 years of your terminal degree in PhD or within 10 years of post-graduate clinical training if MD e.g. fellowship)
- **Can extend ESI status:** family care responsibilities, extended periods of clinical training, extended periods of additional didactic instruction, disability, illness, active duty military service, loan repayment, natural disasters or comparable disruptive factors, COVID (usual 24 mo, can go to 120 mo)
- **ESI status- higher paylines:** As of 9/12/22 NIAID payline for RO1s 10% and for ESIs 14%

NIH New Investigator Policies:

<https://grants.nih.gov/faqs#/early-investigators.htm?anchor=question55019>

Tips from transition from K to R

- **Find your niche:** Exclusive corner of your field where you could conduct research for the next 10 years
 - ▣ Locate most promising research needs and opportunities in your field.
 - ▣ Assess whether you have the skills to make an impact (one or more prior publications should be along this theme)
 - ▣ Look at the other players and judge whether you can compete.
 - ▣ Network with these players; search the literature and people online (those people will be your reviewers). Meet them at meetings, ask a question about their research, follow-up with an email

NIAID Pick a Research Project

<http://www.niaid.nih.gov/researchfunding/grant/strategy/Pages/2picktopic.aspx#a>

Call on us!

- Access resources such as
 - ▣ UCSF CFAR mentoring program
 - ▣ NIH resources – grant writing tips, Rock Talk (<http://nexus.od.nih.gov/all/category/blog/>)
 - ▣ Research mentor and career mentor
 - ▣ Mock study sections/ specific aims lightning rounds



Questions?