

Grant Writing and Early Career Trajectories

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Typical Urgent Alert in My Neighborhood: "Moose On Pinebrook Blvd. Drive Slow."







Objectives

- Early Career Trajectory
 - Tools and Realities
- Grant Writing
 - Most of What I know in an hour or less...

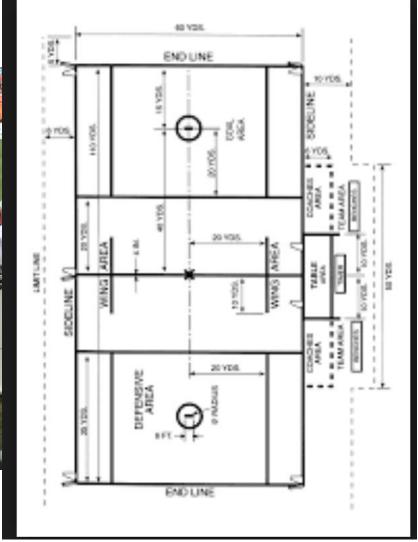
Strategy #1: Know the "Rules" of the Game

- Promotion and Tenure
 - Metrics?
 - Papers
 - Grants
 - H index
 - I 10 index
 - Journal Impact factor Impact on Patient Care
 - Education Products

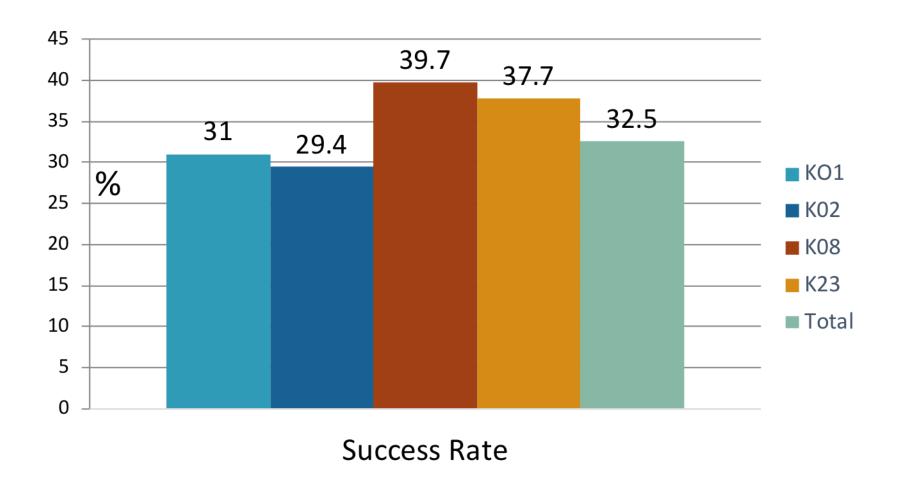
Strategy #2 Know the Playing Field

(Competition)



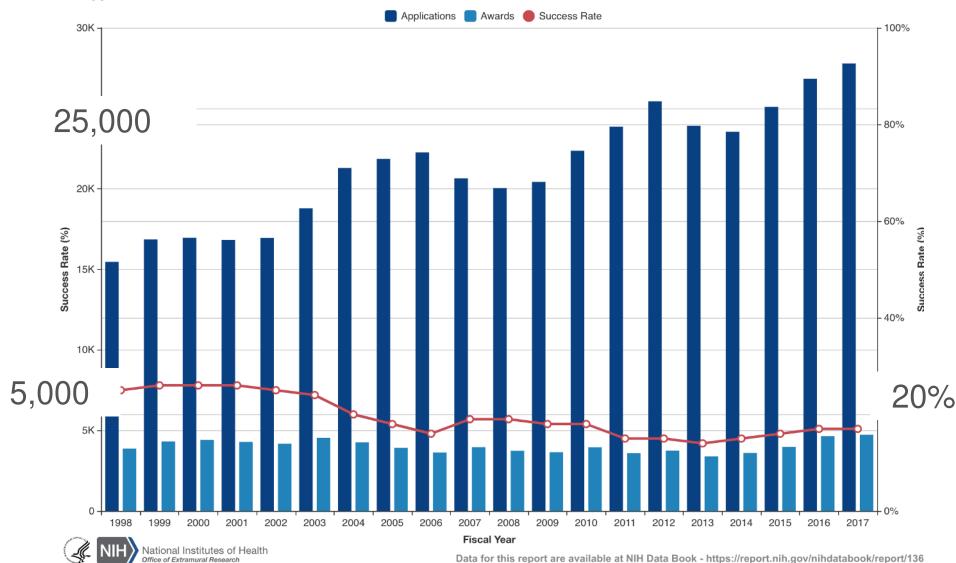


Success rate of NIH K's

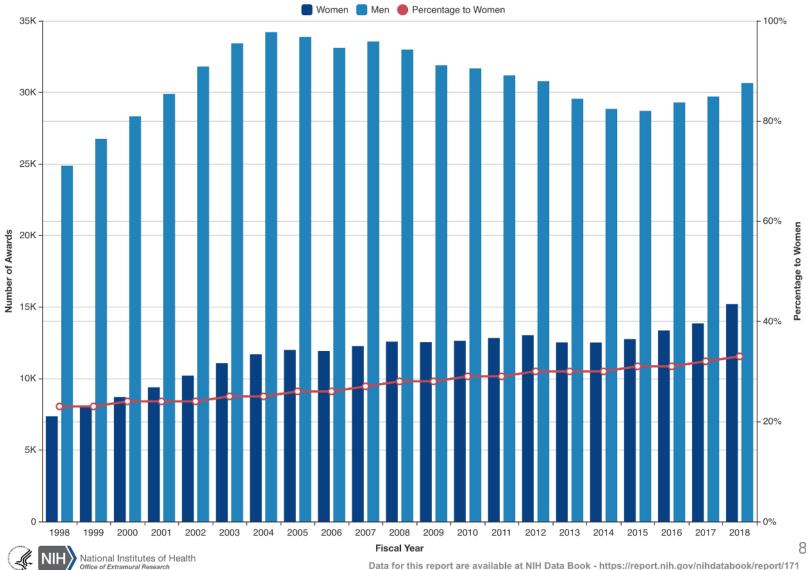


R01 equivalent success rate

All Applications

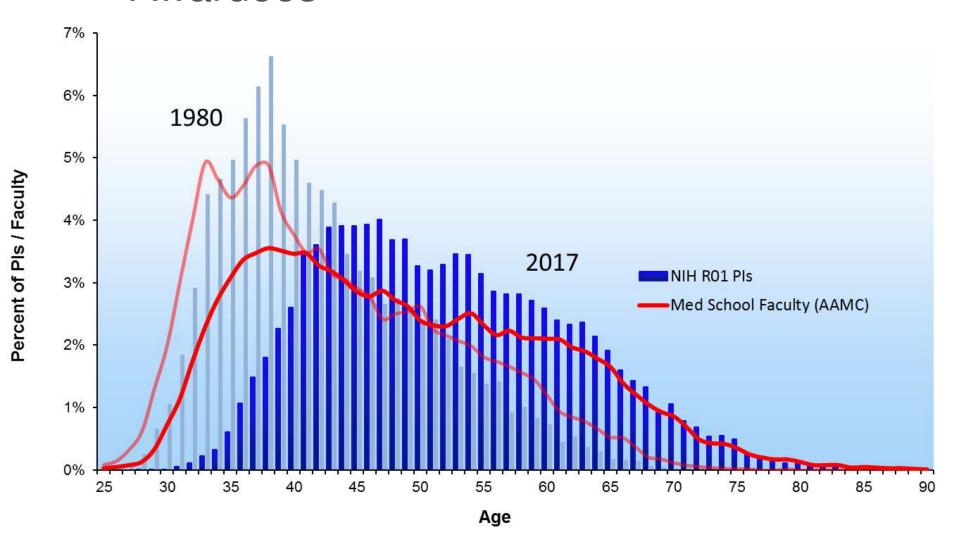


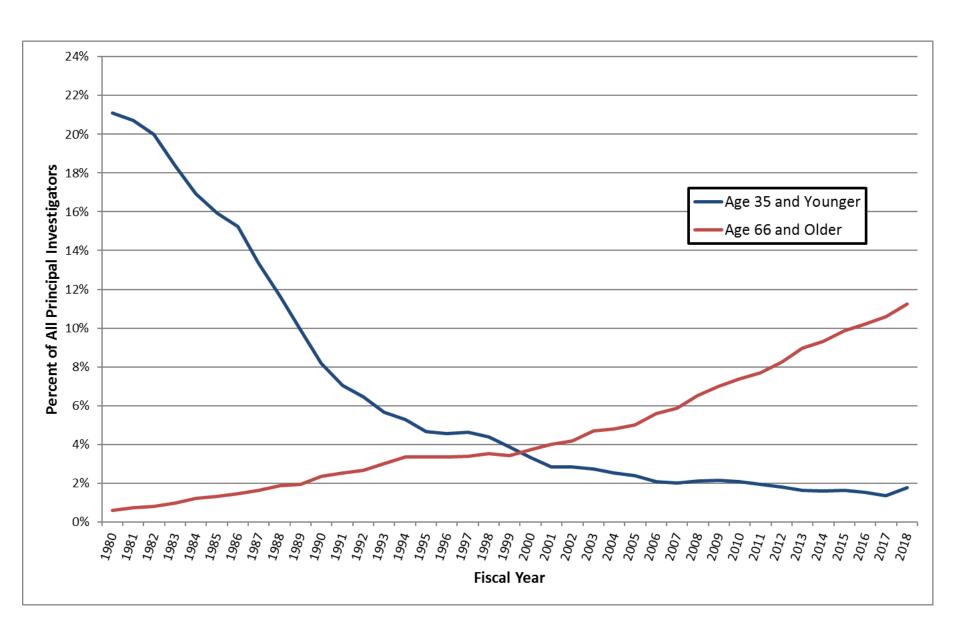
The Gender Gap



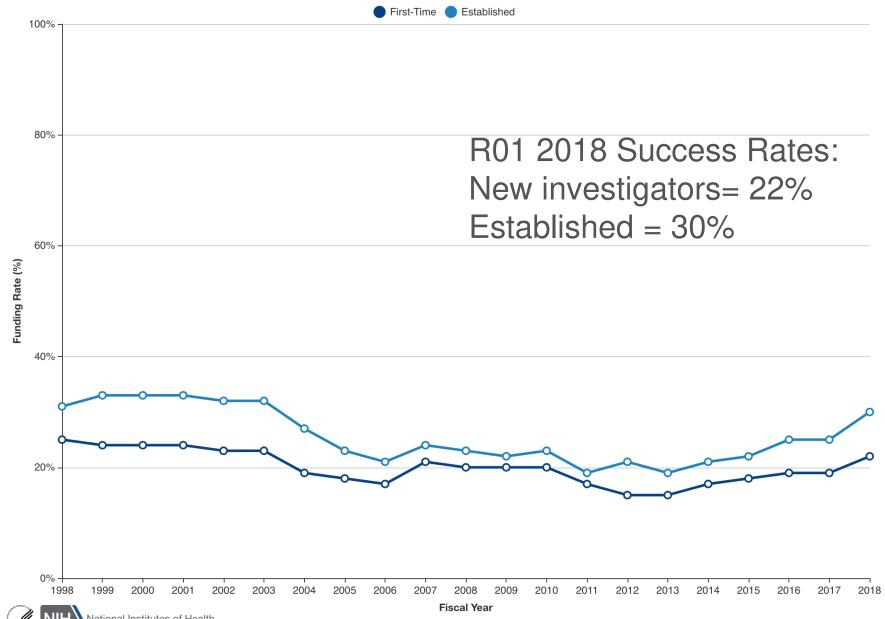
Aging of NIH Awardees

1980 & 2017





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



Should I apply for a K or an R?

- Do I need additional training?
 - Training vs. experience
 - What skills do I lack
- Does my department chair support me?
 - Will provide release time from clinical/teaching duties
 - Will provide needed support (\$) for research
- Do I have mentors who are NIH R01 funded?
- Use the NIH K <u>NIH Career Development Web Page</u>

Strategy #3:Know What's Ahead



How do I avoid the K Cliff? PATH 1 PATH 2

Hire	Instructor	Assistant Professor
0		Submit K
1		
2	Submit K	K Award
	Assistant	
3	Professor	
4	K Award	Submit R01
5		
6		R01 Award
7	Submit R01	K CLIFF/Tenure
8		
9	R01 Award	
10	K CLIFF/Tenure	

When do I submit an R?

- •Do I have the skills?
- •Do I have the right collaborators?
- Do I have preliminary data to support my aims?

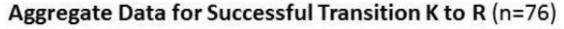
I Just Got A K, Can I submit an R01?

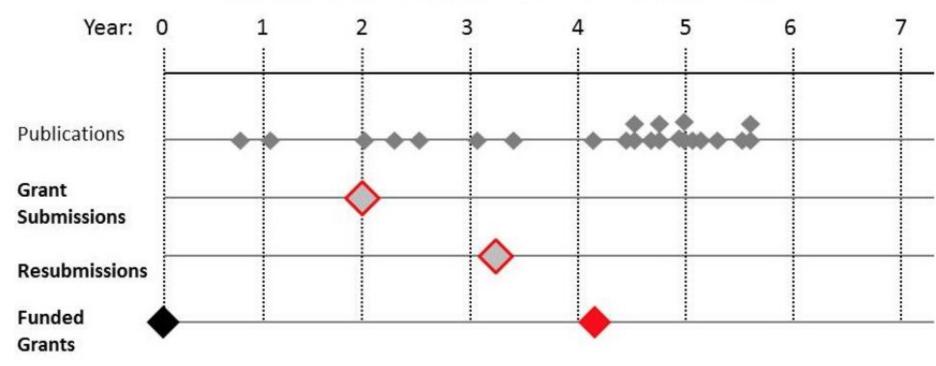
- Do I have preliminary data?
- Do I have the resources and collaborators?



Submit

COLLECT PRELIMINARY DATA ON YOUR K





= K Award
= R01 Award
= R01 Submission

From: Katherine Hartmann, MD, PhD, https://edgeforscholars.org/taking-flight/

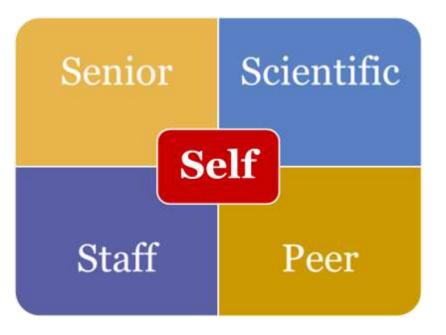
Strategy #4: Be Prepared to Adjust Your Plan

- Take advantage of critical opportunities when they arise.
 - Don't take EVERY opportunity that arises
- Don't submit a grant based on the plan, submit based on the viability of the research
- Solicit feedback on your progress at least annually from your department

Strategy #5 — It Takes a Village

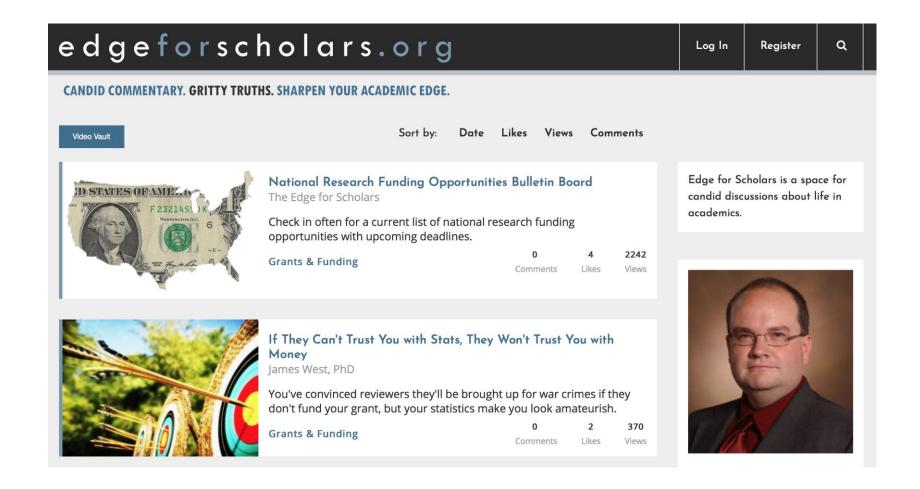
Matrix Mentoring Model

- Have a mentoring team not just a mentor
- Choose new mentors as your interests change



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Early Career Resource



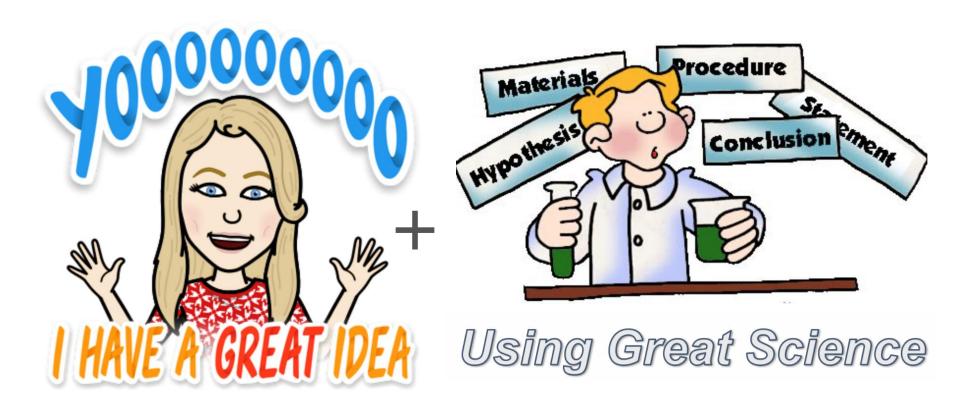
Strategy #6: Get the Intangibles (Other Skills YOU Need)

- Leadership
- Communication
 - Writing
 — NIH Plain Language Tutorial
 - Northwestern CLIMB Writing Resources
 - Presentations
- Grants Management and Research Training
- Mentoring



Grant Writing: Highlights and Strategies

What Does it Take to Have a Successful Grant?



Align Your Idea and Science with the agency's Mission



- MISSION: ".....ENHANCE HEALTH, LENGTHEN LIFE AND REDUCE ILLNESS AND DISABILITY"
- GOALS ARE AROUND
 - IMPROVING HEALTH
 - CREATING AND MAINTAINING RESOURCES TO PREVENT DISEASE
 - ENHANCING THE NATION'S ECONOMIC WELL-BEINGAND A HIGH RETURN ON INVESTMENT
 - PROMOTING THE HIGHEST LEVEL OF SCIENTIFIC INTEGRITY

Funding Announcement Vocabulary

- NIH Requested Research
 - Funding Opportunity Announcement (FOA)
 - Program Announcements (PA)
 - Requests for Applications (RFA)
- Investigator Initiated Research
 - R01 Parent announcement

Writing for Success: Give Yourself Time!

- Reflect & refine your project idea
- Recruit team and secure partners
- Define roles and deadlines
- Gather support data
- Letters of Support/Biosketches
- Obtain commitments and signatures
- Write, Review, Edit, Write, Review, Edit

Writing to the Review Criteria

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Research Grant	Pages	Review Criteria For a Research Grant OVERALL IMPACT
• Aims	1	
 Significance 	1½ to 2½ *	• Significance
Innovation	$\stackrel{1}{\swarrow}$ to 2 $\stackrel{1}{\swarrow}$ *	Innovation
Approach	< 7-10*	• Approach
Biosketch	€ 5	• Investigator
Resources	<pre>no limit</pre>	• Environment
 Budget 	no limit	

^{*}these 3 sections together may not exceed 12 pages

Draft a Specific Aims Page

- One page summary of the proposal
- Start with the knowledge gap problem or scientific gap (1-2 paragraphs)
 - Usually no references
- Lead up to the goal of the proposal-
 - Could include short and long term goals, if appropriate
- Study design and general information about methods to achieve the
- Specific Aims
- What successful completion of the aims will bring to the field, or to the health of Americans or prevention of disease

Send Your Vetted Specific Aims Page to an NIH Project Officer

- Find an NIH Project Officer (PO) from the Institute you will target
 - Ask your mentors who their project officers are
- Request a 15 minute phone call to discuss your specific aims with the project officer
- Ask the PO what study section they suggest you submit to
 - Use the <u>Center for Scientific Review Assisted Referral</u> <u>Tool</u>

Write the Approach Second

- Preliminary data
- Provide an introductory paragraph with the rationale or overview of the aim
 - if a clinical trial do this once and not for each aim
- Specific and detailed methods about how you will carry out each aim.
- Provide a potential pitfalls and alternate approach for each aim or overall.

Common Pitfalls to Address

- Under enrollment
 - Provide details about access to patient populations (number that represents potential for recruitment)
 - Alternate approaches to get more participants
 - Under-enrollment presents a threat to validity: Increases risk of type 1 error with inadequate sample
- Potential for contamination if there is more than one treatment and methods to control.
- Sources of error in data or measures and methods to minimize them
- Specific approaches that might not work

Rigor and Reproducibility: Address the following where applicable

- Vertebrate Animal Species
- How you will assure identity and validity of biological and chemical resources
- Human Subjects Justification and Use in Study Design
 - Sex, age, race and ethnicity and other important biologic variables
- Experimental Design-Rational for design and endpoints
- Criteria for inclusion, exclusion, and attrition
- Plan for reporting all results (Intention to treat)

Rigor and Reproducibility: Cont.

- Justify sample size or Power
- Define the subject (e.g. cell, whole animal or human)
- Describe Statistical Analysis Methods
 - For multiple behavioral interventions justify and describe order for and control of order of testing (randomization)
 - For Drug studies-justify dose and route of delivery
- Minimizing Bias: Address
 - Blinding
 - Randomization

Why Start on Approach After the Aims?

- If methodologic issues arise that require changing the aims you identify it sooner
- The methods determine the budget
 - Budgets over 500K in any year need prior approval
- Approach is the section where most grants receive the worst sub-score
- It's the longest and most difficult sub-section

Significance Section Summary of the literature (with citations) and consideration of their methods that leads to a significant:

- Knowledge gap
- Clinical problem
- Barrier to progress

What Makes a Research Project "Significant"?

"how it will improve health, health outcomes, or quality of life for patients, and /or quality and efficiency of care (patient burden, time or cost-wise)."

Avoid the Laundry List Approach

- A summary integrating the body of literature
- Identify methodologic issues with prior approaches (Rigor of Prior Research).
- Show that you understand the literature
- Distill Literature into the important points
 - Use them support your purpose.

Significance... (cont.)

- Why prior approaches/treatments/theories are unsatisfactory
- If the aims are achieved how will knowledge, technical capability and/or clinical practice be improved
- How will success change the status quo? e.g. the concepts, methods or technology, treatment, services or preventive interventions that drive the field.

What is **NOT** Significance?

- Prevalence, incidence, rates
 - Including is ok, but this doesn't make it significant
- General background information
 - You can include some of this but this alone doesn't establish significance
- A large number of people with the disease
 - without potential to change health, health outcomes, quality of life or cost-effectiveness

Significance vs Background

Significance

- Focused on the scientific gap
- How you frame the problem

Background

- Longer and includes more general information
- Builds to specific information and the scientific gap

Innovation Review Criteria

- Does the application challenge and seek to shift current research or clinical practice paradigms by using novel theories, approaches (method, instruments) or interventions?
- Are the concepts approaches or interventions novel to the field of research or novel in a broad sense?
- Is a refinement of the above proposed?

Do I Have to Use Innovative Methods?

- No
- You have to convince the reviewer that what your work brings to the field is innovative in some way
 - Will change patient care
 - Improve health
 - Prevent disease
 - With be more cost-effective

Use Literature to Frame the Status Quo: Diplomatically

- Don't need to address strengths and weaknesses like you did in significance
- Reviewer might be author of previous work, so be thoughtful and diplomatic
- Give credit for the advance of the prior work while illuminating the opportunity for further advancement

Positive Impact or Change?

- Concepts/Methods/Technologies
 - What we can't do now that might be possible if your work shows what you think it will
- Treatments/Services/Preventive interventions
 - That are or might be possible if your hypothesis is correct
- Outcomes- better, quicker more reliable
- Cost higher quality/value

Tell the Reviewer Why it is Innovative

"The proposed research is innovative, in our opinion, because it represents a departure from the status quo" (how)

Innovation: Include New Horizons

 What areas of research or clinical care will be possible after your aims are successfully completed?

Significance vs. Innovation

- Significance
 - tells what the problem is and why it is important

- Innovation
 - what your research brings to the tableto move the field forward

Biosketch

Generate using SciENcv in MY NCBI

Murtaugh biosketch in SciENcv

Biosketch = Investigator Criterion

- Name and NIH commons ID
- Education and Training
- A. Personal Statement Unique to the Proposal
 - Your story
 - Why you are qualified
 - Summarize relevant prior experience
 - Explain change in direction
 - Explain prior work with co-investigators
 - Include up to 4 citations for this section

B. Position and Honors

- Establishes your record of excellence
- Includer relevant professional memberships
- Editorial Review Boards
- Journal Review
- NIH Study Sections (Permanent)

C. Contributions to Science

- Up to 5 Contributions
- Each describes a body of work
 - Your role
 - Up to 4 citations
- Describe WHAT YOU FOUND
- IMPACT on the field
- NOT just what you did

Citations in the Biosketch

- Bold your name in each citation
- Include PMCID
 - Link to Federal Funding.
 - The PMID is a pubmed ID
 - PMID to PMCID converter
- Refer to citation in the summary (a).
- **a. Murtaugh MA**, Herrick J, Sweeney C, Guiliano A, Baumgartner K, Byers T, Slattery M. Macronutrient composition influence on breast cancer risk in Hispanic and non-Hispanic white women: the 4-Corners Breast Cancer Study. Nutr Cancer. 2011;63(2):185-95. PMCID: PMC4700927.

- 1.→ Redwood DR, Ferrucci ED, Schumacher MC, Johnson JS, Lanier AP, Helzer L, Tom-Orme L, Murtaugh MA, Slattery ML (2008). Traditional food and physical activity patterns and associations with cultural factors in a diverse Alaska Native population. *Int J Circumpolar Health, *674(4), 335-348.¶
- 2.→ **Murtaugh MA**, Sweeney C, Giuliano AR, Herrick JS, Hines L, Byers T, Baumgartner KB, Slattery ML (2008). Diet patterns and breast cancer risk in Hispanic and non-Hispanic white women: The Four-Corners Breast Cancer Study. Am J Clin Nutr, 87(4), 978-84.
- 3.→ **Murtaugh MA**, Curtin K, Sweeney C, Wolff RK, Holubkov R, Caan BJ, Slattery ML (2007). Dietary intake of folate and co-factors in folate metabolism, MTHFR polymorphisms, and reduced rectal cancer. *Cancer Causes Control, *18(2), 153-63. PMCID: PMC2366030¶
- 4.→ Slattery ML, Schumacher MC, Lanier AP, Edwards S, Edwards R, Murtaugh MA, Sandidge J, Day GE, Kaufman D, Kanekar S, Tom-Orme L, Henderson JA (2007). A prospective cohort of American Indian and Alaska Native people: study design, methods, and implementation. *Am J Epidemiol*, 166(5), 606-15.¶
- 1. → **Murtaugh MA**, Herrick J, Sweeney C, Guiliano A, Baumgartner K, Byers T, Slattery M. Macronutrient composition influence on breast cancer risk in Hispanic and non-Hispanic white women: the 4-Corners Breast Cancer Study. Nutr Cancer. 2011;63(2):185-95. PMCID: PMC4700927. ¶
- 2. → Murtaugh MA, Sweeney C, Giuliano AR, Herrick JS, Hines L, Byers T, Baumgartner KB, Slattery ML. Diet patterns and breast cancer risk in Hispanic and non-Hispanic white women: The Four-Corners Breast Cancer Study. Am J Clin Nutr. 2008 Apr;87(4):978-84 PMCID: PMC2409282. ¶
- 3. → Murtaugh MA, Herrick JS, Sweeney C, Baumgartner KB, Guiliano AR, Byers T, Slattery ML. Diet composition and risk of overweight and obesity in women living in the southwestern United States. J Am Diet Assoc. 2007 Aug;107(8):1311-21. ¶
- 4. → Slattery ML, Sweeney C, Edwards S, Herrick J, Baumgartner K, Wolff R, **Murtaugh M**, Baumgartner R, Giuliano A, Byers T (2007). Body size, weight change, fat distribution and breast cancer risk in Hispanic and non-Hispanic white women. *Breast Cancer Res Treat*, 102(1), 85-101. •¶

Biosketch Section D. Listing Research Funding

Do Include

- Funding Agency
- Title of award
- Purpose or Objective of award
- Principal Investigator
- YOUR role

Do not include

- \$ (amount of award)
- person months

Budget

- Start your budget early
 - When you are working through approach
 - Might need to negotiate space/equipment with your department
 - Negotiate effort with co-investigators
 - Subcontracts with individuals outside your U
 - Allow at least a month
- Ask for what you need NOT MORE OR LESS
- Work closely with your pre-award staff

Resources (Quality not Quantity)

- Describe general resources
 - relevant to your appointment
- Specific resources needed to achieve your aims
 - Access to patient populations or animal labs
 - CTSI cores
 - Secure data storage capability
 - Equipment
 - Lab space

Protection of Human Subjects/Animal Welfare

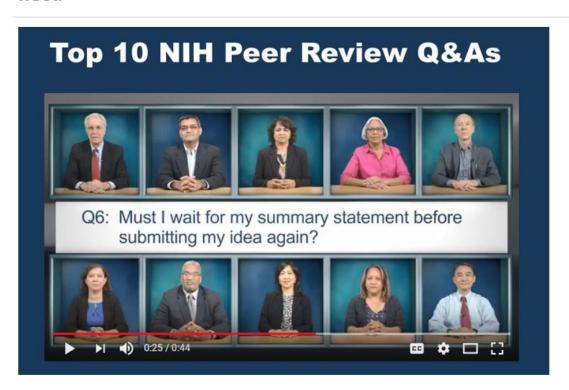
- Award will held if there are concerns about human subjects or animal welfare
- NIH Human Subjects Page

NIH Scoring Vocabulary

- Impact Scores and individual criteria scores are reported from 1 (perfect)- 9 (do not resubmit)
- Impact score *10 = your score (10-90)
 - Not an arithmetic mean of the 5 criteria
- Percentile Rank
 - Where score falls in that study section –allows comparison across study sections
- Payline
 - A percentile rank up to which nearly all R01 applications can be funded

Center for Scientific Review Videos

Top 10 NIH Peer Review Q&As for Applicants give you the answers you need



https://public.csr.nih.gov/NewsAndPolicy/PeerReviewVideos

5 Common Mistakes to Sink Your Grant

- The preliminary data are weak
 - feasibility questioned?
 - validity of the central hypothesis ??
- House of cards:
 - overall success is dependent on an aim that has not been completed yet.
- The grant is too ambitious.
- Aims are not well connected.
- PI and the team are not experienced enough to carry out the grant.

Reality of Writing

Perfect writing does not exist; but effective writing does.

- Stay flexible when writing your proposal.
- Professional writers have editors correct their work
 - non-professional should have help, too.

Response to Review: (1 page) Introduction

- One resubmission allowed (A1)
 - May resubmit as a new proposal after 2 reviews
- Respond to the most critical issues
- Summarize substantial additions, deletions, and changes to the application
- Do NOT have to identify changes in text

Parting Advice

- Start Early and Revise Often
- Listen to Mentors who have Experience Specific to your study section
- There is money for GOOD SCIENCE
- Persistence pays off

Questions?