K Grant Funding (NIH): Get Funded Easier and Faster

Presented by: Christopher Dant, PhD
NIH CAREER (K) DEVELOPMENT PROGRAMS

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“The success of biomedical research rests squarely on the robustness of NIH training programs for the next generation of basic and clinical scientists.”

· J Young Investigators, NIH
NIH Training Incentives

- Modify existing K08/K23 to recruit more MDs
- Expand K99/R00 programs across all institutes
- Increase number of awardees transitioning within 5 years to R01s
- New opportunities in NIH Director’s New Innovator Award, Pioneer Award

NIH Investments In Early PIs

1. Fellowships (F) and T32 Training programs
2. K Awards
3. Director’s New Innovator Award for high-risk, high-reward program ($1.5 M in directs)
4. Early Independence Award ($250k/y for 5 years)
Lecture

- About NIH K awards
- Contents of a K award
  - Candidate Section
  - Research Strategy
- K award reviewer viewpoint

27 NIH Institutes
NIH Institutes

NIH Institutes each have their own:

- Mission
- Budget
- Activities
- Ways of doing things
- Own personality
- K emphasis

When you’re planning to submit a K, check with program directors from different institutes to determine their specific policies and interest in your application.

Career Development Awards (K)

- US Citizens, Non-Citizen Nationals, Permanent Residents (except K99/R00)

- Must devote a minimum of 75% effort to research and career development activities

- Previous NIH Principal Investigators may be Ineligible

- Principal Investigators on R03 or R21 are eligible to apply (except K99/R00)

- Principal Investigators on R01 or subproject Principal Investigators on a P01 are NOT eligible to apply.
# NIH Mentored K’s

<table>
<thead>
<tr>
<th>Program</th>
<th>Description</th>
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</table>
| K01*  | Mentored Research Scientist Development Award  
Career development in a new area of research—3 to 5 years |
| K07  | Mentored Career in Cancer (only NCI)  
Career development of junior investigators with MD/PhD for cancer-focused academic researchers in cancer prevention, cancer control, or the behavioral or population sciences. |
| K08*  | Mentored Clinical Scientist Research Development Award  
Career development for those with clinical doctoral degree in biomedical/behavioral research, including translational research—non-patient research—If patient research, see K23. |
| K22*  | Mentored Transition Career Development (only NCI)  
Career transition award to individual postdoctoral fellows in transition to a faculty position. |
| K23*  | Mentored Patient-Oriented Research Career Development Award  
Development of the independent research scientist for patient research—if not patient-oriented research in biomedical area, see K08. |
| K25*  | Mentored Quantitative Research Career Development Award  
To foster interdisciplinary collaboration in biomedical research by supporting career development experiences for scientists with quantitative and engineering backgrounds. |
| K99/R00  | NIH Pathway to Independence Award  
Provides 5 years’ support in 2 phases:  
I.1-2 years of mentored support for highly promising postdoctoral fellows.  
II. Up to 3 years of independent support contingent on securing an independent research position. |

*Includes award to promote diversity

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# K99/R00: Pathway to Independence Award

- **K99**: Mentored research experience for up to 2 years.
  - Salary + research expenses

- **R00**: Transition to research independence as junior faculty for up to 3 years.
  - Requires offer and acceptance of tenure-track, full-time assistant professor position (or equivalent)

- Applicants: no more than 5 years of postdoctoral research training at the time of initial application or resubmission

- Non-US citizens may apply, but institution must be domestic
New, ESI Defined

New Investigator (NI)
- Has not been PI on a significant NIH research grant (R01)
- Can have held small research grants (e.g., R03, R21), K awards, Fellowships (F)

Early Stage Investigator (ESI)
- An investigator within 10 years of doctorate or completing residency

Status defined in your eRA Commons profile

New Training Website

https://researchtraining.nih.gov/
K Grant Funding (NIH): Get Funded Easier and Faster

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

NIH K Award Contacts (K08)

Mentored Clinical Scientist Research Career Development Award (Parent K08) (PA-16-191)

Table of IC-specific Information, Requirements and Staff Contacts

<table>
<thead>
<tr>
<th>Institute or Center Contacts</th>
<th>Main Contact</th>
<th>Specific Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Cancer Institute (NCI)</td>
<td>Scientific Program Contact: Marcia L. King, Ph.D.</td>
<td>NCI-specific information: Beginning with applications due on June 12, 2019, the K12 NIH award provides support and protected time for mentored early career stage clinician-scientists interested in undergoing training, research and career development experience in the National Cancer Institute's (NCI) intramural cancer research. Mail-in applications must include a career development plan that is a minimum of 2 years with at least 1 year of mentored activities. Applicants must have a Ph.D., M.D., or M.D./Ph.D. degree prior to or during the application period. The maximum federal period of support is 6 years. The maximum federal amount is $2,000,000.</td>
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<tr>
<td></td>
<td>Email: <a href="mailto:marciak@nih.gov">marciak@nih.gov</a></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Office of the Director: Hermagi Hernán-Patron, M.B., B.Ch., M.D., Ph.D.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Email: <a href="mailto:appswire@nih.gov">appswire@nih.gov</a></td>
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</tr>
</tbody>
</table>
**What Mechanism in Your Career?**

- **NRSA Predoc**
  - F30, F31
  - Predoc T32

- **NRSA Postdoc**
  - F32
  - Postdoc T32

- **Grad or Med School**

- **Postdoc or Residency**

- **Early**
  - Pathway to Independence K99/R00
  - Career Transition Award K22
  - Ment Research K01
  - Ment Clinical K08
  - Ment Patient-Oriented K23
  - Ment Quant K25

- **Middle**
  - Midcareer Patient-Oriented K24
  - Independent Scientist K02

- **Senior**
  - Senior Scientist Award K05
  - NRSA Senior Fellow F33

**% NIH K Success 2017**

<table>
<thead>
<tr>
<th>K</th>
<th>TYPE</th>
<th>All NIH</th>
</tr>
</thead>
<tbody>
<tr>
<td>K01</td>
<td>Mentored Research Scientist</td>
<td>31.5</td>
</tr>
<tr>
<td>K07</td>
<td>Academic Career Award</td>
<td>14.5</td>
</tr>
<tr>
<td>K08</td>
<td>Mentored Clinical Scientist Career</td>
<td>43.6</td>
</tr>
<tr>
<td>K22</td>
<td>Career Transition</td>
<td>18.5</td>
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<td>K23</td>
<td>Mentored Patient Oriented Research</td>
<td>34.0</td>
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<tr>
<td>K25</td>
<td>Mentored Quantitative Research</td>
<td>23.5</td>
</tr>
<tr>
<td>K99</td>
<td>Pathway to Independence</td>
<td>23.4</td>
</tr>
</tbody>
</table>

2017 AVERAGE SUCCESS RATE, ALL NIH, ALL K’s 30.6%

*Ave. 2017 R grant=18.7%*
A valuable tool to access any F or K grant.

You should know how to use this website.

For example, search all K awards for “Congestive Heart Failure”

Yields this list
K Grant Funding (NIH): Get Funded Easier and Faster

BEFORE you Write

- Coordinate the application with your mentor’s schedule: the K is a collaboration between you and your mentor
- Be clear on your career development plans and progression
- Have a committee review the application after you’re finished writing

Pay attention to this! ➡
K Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Material Requested</th>
</tr>
</thead>
<tbody>
<tr>
<td>Candidate Information &amp; Career</td>
<td>Candidate background</td>
</tr>
<tr>
<td>Development Plan</td>
<td>Career Goals and Objectives</td>
</tr>
<tr>
<td></td>
<td>Career Development &amp; Training Activities</td>
</tr>
<tr>
<td>Research Plan</td>
<td>Specific Aims + Research Strategy</td>
</tr>
<tr>
<td>Statements of Support</td>
<td>Statements by Mentor, Co-Mentor, Consultants</td>
</tr>
<tr>
<td>Environment and Institutional</td>
<td>Description of Institutional Environment</td>
</tr>
<tr>
<td>Commitment to Candidate</td>
<td>Institutional Commitment to Candidates Research Career Development</td>
</tr>
<tr>
<td>Letters of Reference</td>
<td>3-5 reference letters not from the Mentor/Co-Mentor</td>
</tr>
<tr>
<td></td>
<td>From established scientists (referees) that address candidate’s qualifications, training, interests and potential for becoming an independent scientist</td>
</tr>
</tbody>
</table>

Candidate Section—Now One Attachment

PHS 388 Career Development Award Supplemental Form

<table>
<thead>
<tr>
<th>Section</th>
<th>Material Requested</th>
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<tbody>
<tr>
<td>Introduction</td>
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<tr>
<td>Candidate Section</td>
<td></td>
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<tr>
<td>Research Plan Sections</td>
<td></td>
</tr>
<tr>
<td>1. Specific aims</td>
<td></td>
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<tr>
<td>2. Research Strategy</td>
<td></td>
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<tr>
<td>3. Describe how experience on non-NIH funding opportunities will affect the proposed career development</td>
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</tr>
<tr>
<td>Other Candidate Information - Section</td>
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</tr>
<tr>
<td>Mentor, Co-Mentor, Consultant, Collaborations Section</td>
<td></td>
</tr>
<tr>
<td>1. Name and Relationship Information on Other Candidate or Consultants</td>
<td></td>
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<tr>
<td>2. Letters of Support from Collaborations or Consultants</td>
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<tr>
<td>Environment and Institutional Commitment to Candidate Section</td>
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<tr>
<td>10. Description of Institutional Environment</td>
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<tr>
<td>11. Statement of Intent to Promote Career/Policy Development</td>
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<tr>
<td>Human Subject Sections</td>
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<tr>
<td>12. Statement of Intent to Promote Inclusion</td>
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<td>13. Data Safety Monitoring Plan</td>
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<tr>
<td>14. Statement of Intent to Promote Career and Mentors</td>
<td></td>
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<tr>
<td>15. Statement of Intent to Promote Mentors and Mentors</td>
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</tbody>
</table>
K Award — Candidate Section

2. Career Award Candidate Section

| Candidate’s Background                      |
| Career Goals and Objectives                |
| Career Development/Training Activities During Award Period |

One attachment: CANDIDATE INFORMATION AND GOALS FOR CAREER DEVELOPMENT

Candidate Background

- Detail your professional responsibilities and their relation to proposed K activities
- Your prior training and how it relates to your objectives and long-term career plans
- Your previous research efforts, including any publications, prior research interests, and experience (not detailed in biosketch)
- Trajectory to an independent investigator
- You must commit at least 9 person-months (75% effort) to the career development program and related career development activities
Career Goals/Objectives

- How does the award fit into past and future research career development?
- If there are consistent themes or issues that have guided previous work, make them clear
  - If your work has changed direction, give the reasons
- It is important to justify the award and how it will enable you to develop or expand your research career
  - Include a timeline and plan to apply for subsequent R grant support

Career Goals, Objectives

Your career plan should:

- Show a logical progression from prior research and training experiences to the training and research for award period and on to independent investigator status.
- Justify the need for further career development to become an independent investigator.
- Utilize the relevant research and educational resources of the institution.
Career Goals, Objectives

Detail your deficiencies:

“In the past 5 years, I have made progress in developing my clinical research skills, but there are three critical areas in which I require additional training, mentoring, and experience: (1) multi-disciplinary collaboration with clinical and basic scientists, (2) the design and implementation of prospective study design with involvement in the IPFnet, and (3) advanced study design and biostatistical methodology. In the following section, I present a detailed career development plan designed to enable me to acquire the additional training and mentored research experience I need to address these deficiencies and compete successfully for R01 funding, thereby achieving independence as a clinical investigator.”

Career Development, Training Activities

- Describe new/enhanced research skills and knowledge you will acquire

- For mentored awards, describe structured activities—coursework or technique workshops—which are part of the developmental plan
  - Didactic training AND professional skills training (teaching, mentoring, writing, etc.)

- Discuss each activity, include a percentage of time by year, explain how activity relates to the proposed research and the career development plan

- DETAILS!
Career Development/Training Plan

- Additional technical training, not incremental advances in what you already know
- Didactic training
  - Depends on your educational level and background
  - Traditional and non-traditional training (this course!)
- Professional training
  - What you will need to be an independent scientist
  - Includes communication, mentoring, teaching, management, and leadership skills
  - Think about what your mentor does in his/her career and emulate that!

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Career Development From Funded K08

<table>
<thead>
<tr>
<th>Training Activity</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
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<tbody>
<tr>
<td>Workshops</td>
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<td>AAI Immunology Seminar CSHL Stats Methods Genomics</td>
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<td>Bioinformatics &amp; Computational Biology Courses</td>
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<td>Fundamentals of Epidemiology/Advanced Epidemiology</td>
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<tr>
<td>Linear Regression/Category Data Analysis</td>
<td>(10)</td>
<td>(10)</td>
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<tr>
<td>Computational Systems Biology/Biostatistics Computing</td>
<td>(10)</td>
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<tr>
<td>Next Gen Genomic Data Analytics/Biological Database Mgmt</td>
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<tr>
<td>Machine Learning for Bioinformatics</td>
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<tr>
<td>Courseware Systems Biology Specialization (on-line)</td>
<td>(2)</td>
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<tr>
<td>Conduct of research and ethics</td>
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<tr>
<td>Introduction to Research Ethics course (GRAD CS54)</td>
<td>(10)</td>
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<td>Responsible Conduct of Research and CITI renewals</td>
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<tr>
<td>Grantmanship and career development</td>
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<tr>
<td>Grant Writer's Workshop &amp; Scientific Writing Course</td>
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<td>Conference Attendance</td>
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<tr>
<td>American Society of Tropical Medicine &amp; Hygiene</td>
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<tr>
<td>Gordon Research Conference/Keystone Symposium</td>
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</table>
Mentor/Co-Mentor Statement

1. The plan for the candidate's training and research career development
2. Source of anticipated support for research
3. Extent of supervision/mentoring
4. Anticipated teaching load
5. Plan for transitioning you from mentored stage to independent investigator stage
   - Previous experience as a mentor

3-5 Letters, Uploaded via eRA Commons

- Letters are NOT from your mentor/co-mentor
- Develop effective working relationships with potential investigators providing references
- They should be familiar with your qualifications, training, and interest
- Keep them updated as to your progress
- Make their job easy by providing
  - Current biosketch, reprints
  - Draft of K award
- You may be asked to draft the letter they will sign
K Award
Aims and Research Strategy

K Award—Research Plan

<table>
<thead>
<tr>
<th>Research Plan Section</th>
<th>Add Attachment</th>
<th>Delete Attachment</th>
<th>View Attachment</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Specific Aims</td>
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<tr>
<td>4. * Research Strategy</td>
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</tr>
<tr>
<td>5. Progress Report Publication List (for R01/RENEWAL applications only)</td>
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<tr>
<td>6. Training in the Responsible Conduit of Research</td>
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</tbody>
</table>

Similar structure as R grant but always remember, this is RESEARCH TRAINING
You MUST include a plan for instruction in responsible conduct of research (RCR). Now 1 page outside of the 12.

If you fail to include one or it’s inadequate, your application will be incomplete and won’t be reviewed until you provide an acceptable plan of instruction.

You must include 5 instructional components:

1. Format of instruction
2. Subject matter
3. Faculty participation
4. Duration
5. Frequency

Specific Aims

What do I intend to accomplish and why is it worth funding?
Specific Aims
NIH Requirement

① State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.

② List succinctly the specific objectives of the research proposed, e.g.

- test a stated hypothesis
- create a novel design
- solve a specific problem
- challenge an existing paradigm or clinical practice
- address a critical barrier to progress in the field, or
- develop new technology

Specific Aims

- What specific problem am I studying—what gap in knowledge or unmet need is there that I am filling?

- How am I going to fill that gap/need through my research by very specific aims?

- What do I expect to find?

And how will my research impact the field going forward (i.e., what new information and insights will it give other researchers to move forward in the field?)
Specific Aims: Structure

1. PARAGRAPHS 1—Define the problem/critical need and gap(s) in knowledge—short background leading up to the stated problem and knowledge gap (the “need”)

2. PARAGRAPHS 2—solution to stated problem and gap by proposing hypothesis(es)

3. PARAGRAPHS 3—Specific Aims -Objectives that test the hypotheses addressing the critical need

4. PARAGRAPHS 4 —Payoff
   - **Expected Outcomes** leading to impact on the field
   - **Addressing an NIH need?** If grant is unsolicited.
   - **Impact** probability your study will be successful and will exert a powerful sustained influence on the field
     - If it won’t work, it has no impact, even with high significance
     - Address the immediate problem AND your long-term goals

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**Paragraph 1**

**Important Known’s**

**Unknown’s**

**Unmet Need & Gaps in knowledge**

**The BASIS for your project:**
How will you fill that knowledge gap and fill that need?
Paragraph 1

HOOK your reviewer in first sentence!

1. Background of what is known, what’s unknown, leading to GAP in knowledge.
2. The problem is NOT the disease itself but what gaps in diagnosing or treating the disease that is important.

NO: Little research has been done...there is need for additional work...few studies have been made...no publications have examined the reasons for...

NO: Type II Diabetes currently affects more than 3% of the U.S. population, and is responsible for over 100,000 deaths and $1,000,000 in direct healthcare costs each year. Often, people with the disease manifest open wounds that are resistant to healing.

Paragraph 1

The problem is NOT the disease itself but identifying the gaps in our knowledge that will help us diagnose or treat the disease

NO:
Lung cancer is the leading cause of deaths among men and women in the USA and responsible for 200,000 deaths in 2017 and overall healthcare costs of $21B in 2016-17...

YES:
Although overall rates of cigarette smoking in the U.S. have decreased in the past 20 years, smoking rates have actually increased among low-income women of child bearing age in the past 10 years.
Paragraph 2: Hypothesis

- Must be compatible with all known facts and evidence.

- It must be specific.

- It must be testable (i.e., there’s at least 2 outcomes).

- Your aims will test it.
  - We hypothesize that ... OR
  - Specific Aim 1: To test the hypothesis that...

Paragraph 3: Specific Aims

- Specific aims that are hypothesis-based to address the problem and fill the gap.

- Aims are SPECIFIC, measurable, and do-able in time frame of the grant
Specific Aims are SPECIFIC

DO NOT use non-specific language.

To study the effects of...
To explore the reasons for...
To better understand the effects of...
To investigate the causes of...
To research why...

Specific Aims are SPECIFIC

Aims are specific, measurable objective:

SA 1. Measure levels of calcium and magnesium levels in the wound microenvironment over 21 days using an established animal wound healing model.

SA 4. Determine the normal range of fetal-to-adult T cells in the umbilical cord blood of the full-term neonate.
Paragraph 4

- What are my expected outcomes?

- What is the probability my study will be successful and exert a powerful sustained influence on the field(s) specifically and more generally—impact

- Expected outcomes must be specific and credible—it’s the return on investment for NIH.

- Do not write in the future tense—not “this is what we will have accomplished...” but “We expect to determine X, Y, Z”

- Impact — How will these stated outcomes fill the identified need and thereby advance research (and the mission of the agency, if possible)?
2. Specific Aims
Evidence of Problems in 66 Grants

<table>
<thead>
<tr>
<th>Review Problem</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goals overstated, overly ambitious, unrealistic</td>
<td>45</td>
</tr>
<tr>
<td>Poorly focused, inadequately conceptualized</td>
<td>38</td>
</tr>
<tr>
<td>Hypotheses not clearly articulated</td>
<td>50</td>
</tr>
</tbody>
</table>


Significance

*Why is this work important*
*(to human health and disease)*?
**Significance**
**NIH Requirement**

- What is the importance of the problem or critical barrier to progress in the field that the proposed project addresses?

- How will my work improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields?

- How will the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field be changed if the proposed aims are achieved?

**Significance**
**NEW Requirement**

- Describe the scientific premise for the proposed research, including strengths/weaknesses of published research or preliminary data critical to support your application.
Significance
Recommendations

- Make a compelling case—why is this research important for the field (broadly and more specifically)?
  - Review of published/unpublished work (incl. your own)

- Point out how your research will fill knowledge gaps
  - Show that you are aware of the opportunities, gaps, roadblocks, and research being done

- If possible, tie significance to the mission of the NIH institute — what are their research priorities?
  - Check institute website for research priorities
  - Check institute PAs/RFAs objectives

Innovation

How is this work novel/original?
Innovation—Outline This:
1. How is my work being done now? (i.e., what existing strategies are being used to address the problem?
2. What limitations do these methods have, and why have they not worked?
3. What are the advantages of my approach and what advances will be possible for future research that would have not been possible with the old methods.

Approach
NIH Requirement
① Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project.
② How will data be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate?
③ Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
④ If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work.
Rigor and Reproducibility

- New NIH requirement for all R and mentored K grants.
- Now expectations that ensure NIH is funding rigorous science and increase transparency and scientific rigor.
- Requires more details previously overlooked.
- Does not require new sections in grant.

Approach

New NIH Requirement

1. Describe design and methods and how they will achieve robust and unbiased results.
2. Explain how variables such as sex are factored into research design/analysis in humans and animals.
3. Strong justification from the literature, preliminary data, or other relevant considerations must be provided for applications that propose to study only one sex.
Rigor and Reproducibility

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Writing Your K

- A great program and stellar academic record help, but to get the best score, you need to show reviewers that you can establish a research career.

- Your Career Development Plan is as important as your Research Plan
  - Explain how K will be a vital step toward your ultimate career goal and move you toward scientific independence.
  - Specify training and courses that you will participate in, how often you’ll meet with consultants, and how all of this will help you reach independence.
Writing Your K

- Reviewers will look closely at your Research Plan: Specific Aims and Research Strategy.

- They will evaluate whether it is appropriate for and tailored to your experience level and if it allows you to develop the skills and knowledge needed for further career advancement.

- Make sure you relate the proposed research to your career goals, and you are able to achieve your objectives in the time you request.

5 K Criteria

- Candidate
- Career Development Plan
- Research Strategy
- Environment/Institution Commitment
- Mentor/Consultants/Collaborators
K Referee Instructions

Describe the qualities and potential of the candidate with reference to:

1. Potential for conducting independent productive research
2. Evidence of originality
3. Adequacy of scientific background
4. Quality of research endeavors/publications to date
5. Commitment to health-oriented research
6. Need for further research experience and training

K Review at NIH

- Similar across most institutes
- Some institutes have separate panels for K’s
- Timing shorter to get feedback faster
- All review criteria equally critical—low score on one can hurt proposal
- Percentage of success higher than R’s
**K Overall Impact**

- Does the candidate have the potential to develop as an independent and productive researcher?
- Are the candidate's prior training and research experience appropriate for this award?
- Is the candidate’s academic, clinical (if relevant), and research record of high quality?
- Is there evidence of the candidate’s commitment to meeting the program objectives to become an independent investigator in research?
- Do the letters of reference address these review criteria, and do they provide evidence that the candidate has a high potential for becoming an independent investigator?

**Final Thoughts**

Sample K01 and K08 grants (On NIAID site):

https://www.niaid.nih.gov/GRANTS-CONTRACTS/SAMPLE-APPLICATIONS#k08

Before you begin:

1. Pick a target K award—read the RFA first
2. Contact the Program Officer
3. Form a mentoring team & discuss your candidate & research plan

- **Begin at least 6-8 months ahead of submission date**
- **Solicit reviews of your application!**
- **Final application must be neat, clear, error-free!**
Questions?

Contact:
Christopher Dant
medcomconsul@gmail.com