K Awards: the Next Step

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July 2017
Grants 101

I. NIH Structure & Behind the Scenes at Study Section
   Tom Hawn

II. Introduction to Research Administration at UW
    Monica Fawthrop

III. Training & Career Development Awards
     Sheila Lukehart
NIH and Career Development Awards

- Types of training awards
- Getting information about K’s
- Components of a K application
- Tips on writing a great application
Types of Early Career Training Awards

- MD, DVM, DDS, other Clinical Doctorate
- US citizen, permanent resident
  - K08
  - K23
  - K01
  - K22
  - K25
- Non-citizen/PR
  - Physician/Scientist K99/R00 (NIAID)—NEW!
Types of Early Career Training Awards

- PhD
- US citizen, permanent resident
  - K01
  - K22
  - K25
- Non-citizen/PR
  - K99/R00

Clinical doctoral degree: MD, DVM, PharmD
K08 and K23 Mentored Research Career Development Awards

- **K08** - for basic or lab-based research project
- **K23** - for clinical/patient-oriented project
- **3 - 5 yr award**
  - 3 yrs for more senior individual (e.g. MD MPH; MD PhD)
  - 5 yrs for more junior individual, but must justify a didactic 2 yr phase
- **Salary: $90,000/yr* + Fringe Benefits**
- **Research Support:**
  - $50,000/yr*
  - At least 75% effort committed to research

Health professional doctorate
US citizen, permanent resident
*Varies by institute
K01 Mentored Research Scientist Development Award

- Focus varies by institute*
  - e.g., NIAID limits to epidemiology, modeling techniques, and outcomes research
- MDs or PhDs
- 3 - 5 years
- Salary: $75,000/yr* + Fringe Benefits
- Research Support: $25,000/yr*
- >75% effort on health-related research

US citizen or permanent resident
*Details vary by institute—be sure to look at the information for your own institute
K25 Mentored Research Scientist Development Award

• Focus varies by institute*
  – quantitative (e.g., statistics, economics, computer science, physics, chemistry) and engineering backgrounds
  – Re-focus skills on health and disease
• MDs or PhDs
• 3 - 5 years
• Salary: $75,000/ yr* + Fringe Benefits
• Research Support: $25,000/yr*
• >75% effort on health-related research

US citizen or permanent resident
*Details vary by institute—be sure to look at the information for your own institute
K99/R00 Pathway to Independence Award

- Facilitates transition from postdoc to independence
- Mentored period/Independent period
- MDs or PhDs (New MD award in NIAID)
- <4 years postdoc research experience at initial/re-submission
- 3 - 5 year duration
  - 1-2 yrs Mentored
  - 2-3 yrs Independent
- Details vary by institute
- MDs: Check eligibility criteria for non-independence

NO CITIZENSHIP/PR REQUIREMENT
Details vary by institute—be sure to look at the information for your own institute
K22 Career Transition Award

- Available in some institutes, not others
- Focus varies by institute
- MDs or PhDs
- Must have <5 yrs of postdoc experience
- Provides support (~$250 K total) for the first ~2 years of research as an independent faculty member
- Not mentored—applicant must be “ready to launch!!”

US citizen or permanent resident
Details vary by institute—be sure to look at the information for your own institute
Finding information and contacts at NIH

• Go to NIH Career Development Award page

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

### Part 1. Overview Information

<table>
<thead>
<tr>
<th>Participating Organization(s)</th>
<th>National Institutes of Health (NIH)</th>
</tr>
</thead>
</table>
| Components of Participating Organizations | National Heart, Lung, and Blood Institute (NHLBI)  
National Human Genome Research Institute (NHGRI)  
National Institute on Aging (NIA)  
National Institute on Alcohol Abuse and Alcoholism (NIAAA)  
National Institute of Allergy and Infectious Diseases (NIAID)  
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)  
National Institute of Biomedical Imaging and Bioengineering (NIBIB)  
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)  
National Institute on Deafness and Other Communication Disorders (NICDC)  
National Institute on Drug Abuse (NIDA)  
National Institute of Mental Health (NIMH)  
National Institute of Nursing Research (NINR)  
National Center for Complementary and Alternative Medicine (NCCAM)  
Division of Program Coordination, Planning and Strategic Initiatives, Office of Research Infrastructure Programs (ODIR)  
Office of Behavioral and Social Sciences Research (OBSSR)  
Office of Dietary Supplements (ODS) |

### Funding Opportunity Title

Mentored Research Scientist Development Award (Parent K01)

### Activity Code

K21 Research Scientist Development Awards - Research & Training

### Announcement Type

Release of PA-11-180

### Related Notices

- **June 4, 2014** - Notice NOT-14-074 supersedes instructions in Section III. 3 regarding applications that are essentially the same.
- **May 2, 2014** - See Notice NOT-OD-14-009, Notice of Clarification of Letter of K01 Award Eligibility.
- **February 27, 2014** - See Notice NOT-RE-14-003, Notice of Change to the Duration of Career Development Awards Supported by the NIH.
- **February 3, 2014** - See Notice NOT-HG-14-010, Notice of NIH/OD Participation.

### Funding Opportunity Announcement (FOA) Number

PA-14-044

### Companion Funding Opportunity

None

### Number of Applications

See Section III. 3, Additional Information on Eligibility

### Catalog of Federal Domestic Assistance (CFDA) Number(s)


### Funding Opportunity Purpose

The purpose of the NIH Mentored Research Scientist Development Award (K01) is to provide support and “protected time” (three, four, or five years) of supervised career development experiences in the biomedical, behavioral, or clinical sciences leading to research independence. Although all NIH Institutes and Centers (ICs) use this support mechanism to support career development experiences that lead to research independence, some ICs use this mechanism for individuals who propose to train in a new field or for individuals who have had a hiatus in their research career because of illness or pressing family issues. ICs utilize the K01 award to increase research workforce diversity by providing enhanced research career development opportunities. Recipients are encouraged to contact the relevant NIH staff for IC-specific programmatic and budgetary information. **Table of IC Specific Information, Requirements, and Contacts.**

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**READ THIS CAREFULLY!!**

- Purpose
- Eligibility
- Deadlines
- Page limits
- Links to forms
- Required sections
- Review criteria
- Animal, human subjects info
- Contacts
Things to do ahead of time

• Obtain preliminary data to support hypotheses
• Publish papers
• Develop a good mentoring team
Preparing to write the application

• Read the instructions!
  – Program Announcement—has link to forms
  – SF424 Instructions

  Note Section 7: Specific instructions for K applications

• Be aware of page limits

• Look at grant tutorials online

• Read a successful application (or two!)
How to Get Started

• Administrative Issues--Monica
• Timeline for preparing the application--Monica
• Mechanics: Putting Your Best Foot Forward
• Business pages
• Components of K Applications
• Understanding the review process
Administrative Issues: Their Rules and Yours

- Figure out what kind of application you will be writing
- Read the Program Announcement and Instructions—and read them again!
- Talk with a NIH Training Officer
- Talk with your dept’l or division administrator
Timeline: Writing the application

• Start planning and writing very early
• Talk with the administrator who will assist with application
• Talk with your mentor
• Have your mentor and others read the full application early
## Timeline for Writing a Grant Application

<table>
<thead>
<tr>
<th>Timeframe</th>
<th>Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;4 months ahead</td>
<td>Read NIH website about grants, talk with NIH official, decide on grant mechanism, discuss with mentor and grants administrator</td>
</tr>
<tr>
<td>Week -12 to -14</td>
<td>Think, read, cogitate about career development and research plans</td>
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<tr>
<td>Week -10</td>
<td>Draft Specific Aims, give to mentor, meet to discuss, revise</td>
</tr>
<tr>
<td>Week -6</td>
<td>Give <strong>full</strong> draft of to mentor and others; request letters</td>
</tr>
<tr>
<td>Week</td>
<td>Task</td>
</tr>
<tr>
<td>------</td>
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</tr>
<tr>
<td>-6</td>
<td>Work on business pages (biosketch, equipment, facilities, human subjects, vertebrate animals, biohazards, etc)</td>
</tr>
<tr>
<td>-5</td>
<td>Revise draft</td>
</tr>
<tr>
<td>-3</td>
<td>“Final” draft to mentor</td>
</tr>
<tr>
<td>-3</td>
<td>Begin to route business pages</td>
</tr>
<tr>
<td>-2</td>
<td>Finished text sent to Institutional Grants Office</td>
</tr>
<tr>
<td>-1</td>
<td>Submit to agency</td>
</tr>
<tr>
<td>1</td>
<td>Due Date</td>
</tr>
</tbody>
</table>
Mechanics: Writing the application

- Use formal language—no slang or jargon
- Use correct grammar, punctuation
- No typos!
- Pay attention to required fonts and margins
- Leave white space on the pages-not solid text
Boring—and causes tired eyes......

malaria parasites displayed on infected red blood cells (RBCs) promotes adherence of the RBC to plasma membranes and causes the release of microvesicles. These microvesicles store enzymes, lipids, and other molecules that are necessary for the development of the parasite. The release of these microvesicles into the bloodstream can cause inflammation and damage to the host's tissues. The infected RBCs can also cause a condition known as malaria fever, which is characterized by a high fever, chills, and sweats.

We will study the role of the E6 protein in the interaction of the parasites with the host's immune system. The E6 protein is a key player in the pathogenesis of malaria, and understanding its function could lead to the development of new treatments to prevent and treat this disease.
Visual Appeal

- Open space
- Clear organization
- Use of **Bold**, **CAPITALS**, underlining to define sections
Visual Appeal

- Figures and flow charts to explain experimental design

immuno-suppressive treatment, compared to the untreated group. We will compare the specific V-region titers and rate of variation in that V-region to determine whether there is a positive correlation between measurable immunity and variant acquisition.

LIMITATIONS AND ALTERNATIVE PROCEDURES: As discussed in Aim 1, we do not anticipate having difficulty in obtaining enough T polyclonal DNA from the treated to complete the proposed experiments. The same limits, with regard to the sensitivity of detecting variants that are present in low frequency, apply to these studies. Again, however, this may make it more difficult for us to demonstrate an accumulation of variant sequences and will make any positive finding even more meaningful.

Specific Aim 3: Determine whether immune pressure selects for organisms with variant tprK sequences [02, 04].

RATIONAL: If variation of the TprK V regions has significance for persistence, one must hypothesize that these organisms display a variant TprK antigen which may have selective advantages in the face of an ongoing immune response. We will test this hypothesis using information gathered in Aim 1 concerning the relative rate of variation of different region. We will first test whether immunity to the most diverse V region (e.g., W6) is more effective against organisms expressing that V region than immunity against the least diverse V region, V1. Again, these experiments will take advantage of our ability to derive clonal isolates with defined V regions.

EXPERIMENTAL APPROACH: Two experimental approaches will be used to examine our hypothesis that anti-TprK V-region immune pressure will select against sequences expressing these V-regions: 1) the effects of immunization with specific V regions, followed by in vitro selection and characterization of clones expressing these sequences, or 2) the effects of immunization with cloned variants raised against specific V-region variants. The experiment proposes the following:

1. Immunization with V regions: Groups of 3 rabbits each will be immunized with synthetic peptides representing each of the 9 V regions of Chicago Clone 1C. These rabbits and a sham-immunized control group will be challenged...
Business “Stuff”

• Cover letter/Assignment request
• Abstract, Project Narrative
• Face page
• Budget
• Budget Justification
• Resources, Equipment, Facilities
  – Include Biohazards!!!!
Components of K Applications

• Specific Aims (1 page)
• Candidate Section*
• Mentor’s statement, Co-Mentors (6 pages)
• Environment & Institutional Commitment to Candidate (1 page each)
• Research Plan*
• Human Subjects
• Vertebrate Animals

*12 page limit
“Extra” Required Components for K’s

- Biographical Sketch for Candidate
- Biographical Sketches for Mentor, Co-mentors
- Mentor’s Statement*
- Current & Pending Support for Mentor*
- Co-mentor statements*  
  * Max 6 pages
- Letters of Reference
  - 3-5 letters from well-established scientists familiar with the candidate
  - May not be directly involved with the application
Biosketch

Tips and Pet Peeves

- Keep the Personal Statement succinct
- Make it clear when you joined the lab
- Do not follow the NIH example

- Honors—nothing from high school!!

- Contributions to Science—include publications
  - Up to 5 contribution areas, with supporting publications
  - Complete citations, all authors
  - Name changed? Let us know.
  - List link to My Bibliography, with total number of publications, # as FA

- Some leeway is OK for new investigators
  - OK to include manuscripts submitted and in preparation (clearly identify as such!!)
  - OK to add another heading for abstracts (e.g., Presentations)
Required Components for K’s

- Select Agents
- Consortium/Contractual Arrangements
- Letters of Support (Collaborators)
- Resource Sharing Plan
- Reproducibility and Authentication of Reagents--New
Page limits—12 pages!!

• Specific Aims* (1 page)

• Candidate Section
  – Background
  – Career Goals and Objectives
  – Career Development/ Training Activities
  – Training in Resp. Conduct of Research*
    (1 page)

• Research Strategy
  – Significance
  – Innovation
  – Approach

* NOT included in the 12 page limit!!!
Candidate Section

- Candidate’s Background
  - How did you get where you are?
  - What inspired you?
  - More than science
  - Let the reviewers get to know you
Candidate Section

• Career Goals and Objectives
  – Where do you want to be in 5, 10, 20 years?
  – Assess your own strengths & weaknesses
  – What do you need to learn to achieve your goals?
Candidate Section

• Career Development/Training Activities
  - How will this award fill your training gaps?
  - Didactic coursework (req’d for 5 years)
  - Technical training
  - What will you be able to take with you to write an R01?
  - Timeline
Candidate Section

• Career Development/Training Activities
  – Training in manuscript & grant writing, manuscript reviewing, budget and lab management, directing staff/students
  – Attending scientific meetings, journal clubs
  – Presenting work orally, posters
  – Networking at meetings, conferences
  – Measuring progress to independence
Candidate Section

• Training in the Responsible Conduct of Research
  - Provide details per new requirements: format, topics, faculty participation, duration, frequency
  - Future plans for RCR training
  - 1 page (not counted in limit)
Statements of Support (6 pages total)

• Mentor’s statement should include
  – Evidence of successful training history (table of past trainees and current positions)
  – Evidence of active productive research
  – Evidence of support for proposed research
  – Details about mentoring—e.g. frequency of meetings, etc
  – Topic areas in which mentoring will occur
  – Plan and metrics for transitioning candidate to independence

• Co-Mentors’ statements should be specific about the expertise that they bring to the mentoring team

• Co-mentors are different from collaborators
Environment & Institutional Commitment to the Candidate

• Description of Institutional Environment (1 page)
  – Intellectual environment
  – Available facilities, resources relevant to application

• Institutional Commitment to Candidate’s Research Career Development (1 page)
  – Usually letter from Chair/Division Head
  – Guarantees >75% protected time for research training
  – Lab space, office, academic appointment
The Science: Last But Certainly Not Least!

- Schedule uninterrupted time to sit and think—days of time
- Keep a notepad handy to jot down your thoughts and ideas
- Think about the unknowns in the topic that you are studying
- Read the latest papers in your field as well as some well-written review articles—know the literature!!
The Science: It comes together....

- Think in the shower
- Think as you walk around Green Lake
- Think as you work out at the gym
- Begin to see connections and patterns among your ideas
- Follow your heart as well as your mind
The Science: It comes together....

- Explore the most intriguing lines of research further—read related literature from other fields
- Synthesize the information
- Put “your disease” in the context of others
- Forest and trees...
Research Plan

• Specific Aims—1 page (not in 12-page limit)
• Research Strategy
  – Significance
  – Innovation
  – Approach
Specific Aims

• The most important page in the application
• It is a one page summary of the application
  – Why is this problem significant?
  – What is the hypothesis(es), and what data support it?
  – What are the exciting new preliminary data that support your aims?
  – What are you going to do?
  – What will your results mean for the field?
Specific Aims—1 page!!

• List your aims simply
  – Be somewhat general
  – Avoid long (laundry) list of things you are going to do
  – 2-4 Specific Aims is sufficient
• Everything should not be dependent upon Aim 1
• Aims serve as the backbone of your Research Plan
Significance (Background)

• Assume you are not writing for an expert
• Emphasize general medical importance and then specific importance of your topic
• Identify gaps in knowledge; state how you will fill those gaps
• Tie the background to each Specific Aim
• Discuss relevant controversies in the field if relevant
• Avoid selective citation of the literature
• No limit on number of citations
Innovation

• What is new about your idea?
• Will it change the way people think about the topic?
• How will your results affect the future of research in your field?
• Will it affect research in other fields? Paradigm-shift?
• Simply using a new method is not innovative
Approach: Research Design and Methods

• Organize by Specific Aim
  − Rationale and Hypothesis
  − Preliminary data
  − Experimental Approach
  − Expected Results & Interpretation
    − Statistical analysis, sample size
    − Relate expected results to the question
  − Potential Pitfalls and Alternative Approaches

• Other Important Sections
  − Future Directions
  − Timeline
  − Biohazards (Now included in Facilities section)
Approach: Preliminary Studies

• Show preliminary data relevant to each aim and clearly tie the data to the aim (highlight your data)
• Show data for critical methods
• Include control data
• Use ~ 3-4 readable figures or tables
• Convince reviewer that you can do (or will learn) what you propose
• Critically analyze the preliminary data and state how your proposal will clarify questions about it
Approach: Preliminary Studies

• Put figures on relevant pages
• Number figures and tables
• Refer to the number in the text in bold (Fig. 1)
• Figures should be self-explanatory
  – legends, labeled axes, colors, etc.
Approach: Research Design & Methods

- Justify choice of methods
- Details of methods are unimportant (boring)
  - But make sure the reviewers know *you* know the methods
- Get collaborators and consultants - strong letters
- Timeline

<table>
<thead>
<tr>
<th>Aim</th>
<th>Description</th>
<th>YR 1</th>
<th>YR 2</th>
<th>YR 3</th>
<th>YR 4</th>
<th>YR 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>1A</td>
<td>Role of matrilysin in ischemia-reperfusion repair</td>
<td></td>
<td></td>
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<tr>
<td>1B</td>
<td>Neutrophil activation <em>in vivo</em></td>
<td></td>
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<tr>
<td>2A</td>
<td>Neutrophil binding to KC/syndecan-1 complexes</td>
<td></td>
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<tr>
<td>2B</td>
<td>Requirement of syndecan-1 shedding</td>
<td></td>
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<tr>
<td>2C</td>
<td>Syndecan-1 association with integrins</td>
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<tr>
<td>3A</td>
<td>Binding sites of KC:syndecan-1 interaction</td>
<td></td>
<td></td>
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<tr>
<td>3B</td>
<td>Neutrophil activation with disrupted KC/syndecan-1.</td>
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</tr>
<tr>
<td>3C</td>
<td>Inhibit KC/syndecan-1 interaction <em>in vivo</em></td>
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</tr>
</tbody>
</table>
Other Considerations

• Be thorough in addressing all questions
  – Humans subjects
  – Vertebrate Animals

• Address or state “Not applicable” to all categories
  – Select Agents, Resource Sharing, etc

• Bibliography
  – Correct format—list all authors
Scored Review Criteria

- Overall Impact
- Candidate
- Career Development Plan
- Research Plan
- Mentor(s), Consultants, Collaborators
- Environment & Institutional Commitment
Additional Review Criteria*

- Training in Responsible Conduct of Research
- Protection for Human Subjects
- Inclusion of Women, Minorities & Children
- Vertebrate Animals
- Biohazards

* These criteria CAN affect the score
How do you know whether your application will be funded?

- Priority score posted on NIH Commons a few days after review
- Summary Statement 3-6 weeks later
- Paylines are posted by Institutes
- Paylines shift during the FY
What if you are not funded the first time?

- Read the comments carefully and put them away
- Read the comments again 3-5 days later
- Don’t get discouraged
- Discuss options with your mentor
- Revision—one revised application can be submitted
- Listen to what the reviewers said!!!
Don’t give up!!

- Unfunded first applications are common
- Learn from an unfunded submission & succeed next time
  - Study criticisms in Summary Statement
  - Decide whether the problems are reparable
  - Attend diligently to each criticism
  - Keep a positive tone and attitude
- “Good” amended applications tend to do well
Response to Critiques- When you submit a revised application

One page Introduction

• Restate each criticism and explain how you revised the application in response—make it easy for reviewer to find your “answers” by using a different font for revisions

• Misunderstandings are your fault—if the reviewer missed a key fact in a figure or table, maybe it wasn’t clear enough
Response to Critiques- When you submit a revised application

• Be diplomatic and positive (most reviewers’ comments are useful)
• Don’t argue with reviewers
• Avoid tone that says “The reviewer didn’t know anything about this area”
• Avoid overstating your data
The Rewards!

• Discovery!
• Help to understand, control, prevent, or cure a disease
• Opportunity to develop the next generation of outstanding scientists