We love to hear from you!

Please connect anytime.
Our Focus

- Speeding science to the clinic for the benefit of patients and communities throughout WWAMI

- We promote the translation of scientific discovery to practice by:
  - Fostering innovative research
  - Cultivating multi-disciplinary research partnerships
  - Ensuring a pipeline of next-generation researchers through robust education and career development programs
Sheila A. Lukehart, PhD

**Professor** of Medicine and Global Health  
**Adjunct Professor** of Microbiology  
**Director**, UW STD & HIV Research Training Program  
**Associate Dean** for Research & Graduate Education, UW

She is a recognized expert on syphilis and Treponema pallidum, and has focused her research on molecular pathogenesis of syphilis, host immune responses to Treponema pallidum, neurosyphilis, syphilis-HIV interactions, and antibiotic resistance in T. pallidum.
K Awards: the Next Step

Sheila Lukehart
March 25, 2016
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
Overview of Relevant K Awards—Early Career

- **K08  Mentored Clinical Scientist Research Career Development Award**
  - Laboratory focused research
  - May use human samples

- **K23  Mentored Patient-Oriented Research Career Development Award**
  - Patient-oriented research
  - Must be directly involved in interacting with subjects

Clinical doctoral degree: MD, DVM, PharmD
US citizen, permanent resident
Overview of Relevant K Awards—Early Career

► **K22  Career Transition Award**
  ◦ Move from a postdoctoral research position to an independent research position—not mentored

► **K99/R00  Pathway to Independence Award**
  ◦ Transition from a mentored postdoctoral research position to a stable independent research position with independent NIH or other independent research support

PhD or MD (or other health-related doctorate)
US citizen, permanent resident (except K99/R00)
Overview of Relevant K Awards—Early Career

- **K01** Mentored Research Scientist Development Award
  - Used differently by different institutes. e.g., NIAID limits to epidemiology, modeling techniques, and outcomes research

- **K02** NIH Independent Scientist Award
  - Provides 3-5 years of salary support and “protected time” for newly independent scientists who can demonstrate the need for a period of intensive research focus as a means of enhancing their research careers.

- **K25** Mentored Quantitative Research Career Development Award
  - Quantitative or engineering degree moving to health-related topics

  PhD or MD (or other health-related doctorate)
  US citizen, permanent resident
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

*Varies by institute

Health professional doctorate
US citizen, permanent resident
Focus varies by institute

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.
K22 Career Transition Award

- Available in some institutes, not others
- Focus varies by institute
- MDs or PhDs
- Provides support (~$250K total) for the first ~2 years of research as an independent faculty member
- Not mentored

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
- 3 - 5 years
  - 1-2 yrs Mentored
  - 2-3 yrs Independent
- Details vary by institute

US citizen or permanent resident
Details vary by institute—be sure to look at the information for your own institute
Go to K Kiosk and click on the desired award

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

READ THIS CAREFULLY

- Purpose
- Eligibility
- Deadlines
- Page limits
- Links to forms
- Required sections
- Review criteria
- Animal, human subjects info
- Contacts

Part 1. Overview Information

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

Special Note: Because of the differences in individual Institute and Center (IC) program requirements for this FOA, prospective applicants strongly encouraged to refer to the Table of IC-Specific Information, Requirements and Staff Contacts, to make sure that their application is responsive to the requirements of one of the participating ICs.

Funding Opportunity Title

Mentored Research Scientist Development Award (Parent K01)

Activity Code

K01 Research Scientist Development Award - Research & Training

Announcement Type

Reissue of PA-14-044

Related Notices

- See Notice NOT-CA-14-029. Notice of Clarification of Cancer (K) Award Eligibility.
- See Notice NOT-TB-14-003. Notice of Change to the Duration of Career Development Awards Supported by the NIH.

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)

93.242, 93.200, 93.250, 93.340, 93.213, 93.279, 93.838, 93.335, 93.217, 93.021, 93.200, 93.351, 93.173, 93.305

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) for an individual with limited career development experience (in the biomedical, behavioral, or clinical sciences leading to research independence). Although all of the participating Institutes and Centers (ICs) use this support mechanism to support career development experiences that lead to research independence, some ICs use the K01 as an opportunity for an individual with limited career development experience to enter into research independence. Additional information on eligibility and application requirements for each IC can be found in the Table of IC-Specific Information, Requirements and Staff Contacts.
Things to do ahead of time

- Obtain preliminary data to support hypotheses
- Publish papers
- Develop a good mentoring team
- Courses and Compliance
  - Human subjects training
  - Animal training
  - EH&S training
Preparing to write the application

- Read the instructions!
  - Program Announcement
  - 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: Their Rules and Yours
- Timeline for preparing the application
- Mechanics: Putting Your Best Foot Forward
- Business pages
- Components of K Applications
- Understanding the review process
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>&gt;4 months ahead</th>
<th>Read NIH website about grants ahead</th>
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<tbody>
<tr>
<td></td>
<td>Talk with NIH official</td>
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<tr>
<td></td>
<td>Decide on grant mechanism</td>
</tr>
<tr>
<td></td>
<td>Discuss with your mentor and grants administrator</td>
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</tbody>
</table>

| Week -12 to -14 | Think, read, cogitate about career development and research plans |

| Week -10        | Draft Specific Aims, give to mentor, meet to discuss, revise |

| Week -6         | Give **full** draft of to mentor and others; request letters |
Timeline for Writing a Grant Application

Week -6  Work on business pages (biosketch, equipment, facilities, human subjects, vertebrate animals, biohazards)

Week -5  Revise draft

Week -3  “Final” draft to mentor

Week -2  Finished text sent to Institutional Grants Office

Week -1  Submit to agency

Due Date  It’s there on time!!!
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
malarial parasites displayed on infected red blood cells (iRBCs) promotes adherence of the ABC to plasmodium vivax sporozoites, suggesting that the ABC may have potential as a new therapeutic target. In addition, the 3D prints show that the nanotubes are effective in inhibiting the growth of the malarial parasites in vivo. These findings suggest that the ABC may be a promising target for the development of new antimalarial drugs.

(Boring—and causes tired eyes……)
Visual Appeal

- Open space
- Clear organization
- Use of **Bold**, CAPITALS, underlining to define sections
- Figures and flow charts to explain experimental design
**Visual Appeal**

- **Open space**
- **Clear organization**
- **Use of Bold, CAPITALS, underlining to define sections**
- **Figures and flow charts to explain experimental design**

---

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

**Specific Aim 3:** Determine whether immune pressure selects for organisms with variant trpE sequences.

**RATIONAL:** The transition of the trpE region has significance for persistence, one must hypothesize that those organisms displaying the variant trpE antigen will have a selective advantage in the face of an ongoing immune response. We will test this hypothesis using information gathered in Aim 1 concerning the relative rates of transition of functional regions, and will first test whether the immunity to the most diverse V region (e.g., V6) is more effective against organisms expressing that V region than is 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-trpE region immune pressure will select against trpE region expressing clones. The first is the evaluation of the effects of immunization with specific V regions, followed by a challenge with trpE region expressing clones of T. pallidum that vary in the sequence of the V region. The second approach involves the use of selected variants and involves selective pressure against specific V region sequences. The experiments proposed in aim 3 will focus initially on the Chicago Clonal isolates that we already have in hand, additional experiments will be conducted using clones from Sea61-4 and the NIH strain to test the generalizability of our findings.

**Aim 3a:** Immunization with V region: Groups of 3 rabbits each will be immunized with synthetic peptides representing each of the 7 V regions of Chicago Clonal C. These rabbits and a sham-immunized control group will be challenged...
Business Pages

- Cover letter
- Abstract, Project Narrative
- Face page
- Budget
- Budget Justification
- Resources, Equipment, Facilities
“Extra” Required Components for K’s

- Biographical Sketch for Candidate
- Biographical Sketches for Mentor, Co-mentors
- Mentor’s Statement
- Current & Pending Support for Mentor
- Letters of Reference
  - 3-5 letters from well-established scientists familiar with the candidate
  - May not be directly involved with the application
Biosketch—Note New Format 5/15

Tips and Pet Peeves

• Keep the Personal Statement succinct
  • Make clear when you started your time in the lab
  • Do not follow the NIH example

• Honors—nothing from high school!!

• Contributions to Science—including 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

- 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
Required Components for K’s

- Select Agents
- Consortium/Contractual Arrangements
- Letters of Support (Collaborators)
- Resource Sharing Plan
- Appendix (optional—read the rules)
Page limits—12 pages!!

› Specific Aims* (1 page)
› Candidate Information
  - 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?
  - More than science
  - Let the reviewers get to know you

- 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?
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
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
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)
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—frequency of meetings
- 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 critical 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
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
- About 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; refer to figure number in the text in bold (Fig.1)
- Figures should be self-explanatory—legends, labeled axes, 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
- Biohazards

<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>
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<tbody>
<tr>
<td>1A</td>
<td>Role of matrilysin in ischemia-reperfusion repair</td>
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<tr>
<td>1B</td>
<td>Neutrophil activation <em>in vivo</em></td>
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<tr>
<td>2A</td>
<td>Neutrophil binding to KC/syndecan-1 complexes</td>
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<tr>
<td>2B</td>
<td>Requirement of syndecan-1 shedding</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>
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<tr>
<td>3B</td>
<td>Neutrophil activation with disrupted KC/syndecan-1</td>
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<tr>
<td>3C</td>
<td>Inhibit KC/syndecan-1 interaction <em>in vivo</em></td>
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</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
Thank You
Questions?
Visit ITHS.org to Become an ITHS Member
Join a unique catalyst that accelerates discoveries to practice.

Access
Members gain access to the different research services, resources, and tools offered by ITHS, including the ITHS Research Navigator.

Education and Training
Members can access a variety of workforce development and mentoring programs and apply for formal training programs.

Funding
Members can apply for local and national pilot grants and other funding opportunities. ITHS also offers letters of support for grant submissions.

Collaboration
Members can connect with collaborators across the CTSA consortium.
Upcoming Career Development Series

Successful Grant Writing Strategies for an R Award
Ian de Boer, MD, MS
April 29, 2016
Room K069
University of WA Health Sciences

RSVP at ITHS.org