Writing Your K-Award

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On behalf of the ACR Early Career Investigator (ECI) Subcommittee
Outline

• What is a K-award?

• What are the parts?

• What are the steps in preparing your K-award application?

• What happens if you’re not funded the first submission?

• Before you even start, what should you be thinking about?

• General tips and thoughts from the ACR ECI Subcommittee
What is a K-award?

• Mentored Career Development Award
  - K08: clinical scientist development award
  - K23: patient oriented career development award

• Protected time

• Some research support

• **GOAL:** Develop *Successful, Independent Investigators*
What’s important in the K-award?

• You
• Your Mentor
• Your Environment
• Your Research
Anatomy of a K-award

Candidate Background

Career Goals

Career Development Plan

Research Plan

Supporting Documents
Biosketch
Facilities and Resources
Budget/Budget Justification
Cover letter
Project summary (abstract)
Project narrative (public health statement)
Mentor Other Support pages
Equipment

Institutional Environment

Reference Letters

Letters of Support (Mentor)

Training in the Responsible Conduct of Research

Research and related performance sites
Resource sharing plan
Consortium/contractual agreements
Human subjects and/or vertebrate animal and/or selected agents research

Advancing Rheumatology!
SF424 (R&R)

Application Guide for NIH and Other PHS Agencies

A guide developed and maintained by NIH for preparing and submitting applications via Grants.gov to NIH and other PHS agencies using the SF424 (R&R)

Adobe Forms Version B Series (to be used with FOAs specifying use of Adobe-Forms-B-1 and B-2 application packages)

Updated July 25, 2013
You: Candidate Background

- Prior Training

- Evidence of productivity to date (i.e. publications)

- Commitment to research

- Potential as an independent investigator
Review Criteria: The Candidate

• Does the candidate have the potential to develop as an independent and productive researcher?

• 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?

• Do the letters of reference from at least three well-established scientists address the candidate's potential for becoming an independent investigator?
Career Goals and Objectives

• What do you want to do with your life?

• How did you get to those goals?

• Need for further development

• How does the k-award help you reach your goals?
Career Development Plan

• What will you need to do to gain the skills necessary to be an independent investigator and accomplish your career goals?

• Your plan for additional training:
  ▪ Courses
  ▪ 1:1 training
  ▪ Conferences
  ▪ Faculty advancement

• How will you be evaluated? How will you know you’re meeting your goals?
Review Criteria:

Career Goals/Career Development

- Are the candidate's prior training and research experience appropriate for this award?

- What is the likelihood that the plan will contribute substantially to the scientific development of the candidate leading to scientific independence?

- Are the content, scope, phasing, and duration of the career development plan appropriate when considered in the context of prior training/research experience and the stated training and research objectives for achieving research independence?

- Are there adequate plans for monitoring and evaluating the candidate's research and career development progress?
Training in the Responsible Conduct of Research

• Document prior training

• Document plan to get 8 contact hours for every 4 years (10 hours for a 5 year award)

• Your institution likely has a series of seminars on these topics
Training in RCR:

See website for more info

Notice Number: NOT-OD-10-019

Update: The following update relating to this announcement has been issued:

- April 19, 2011 - See Notice NOT-RR-11-005 This Notice updates the requirement for Training in the Responsible Conduct of Research (RCR) with respect to NCRR Science Education Partnership Award (SEPA) (R25) applications.

1. Format: Substantial face-to-face discussions among the participating trainees/fellows/scholars/participants; a combination of didactic and small-group discussions (e.g. case studies); and participation of research training faculty members in instruction in responsible conduct of research are highly encouraged. While on-line courses can be a valuable supplement to instruction in responsible conduct of research, online instruction is not considered adequate as the sole means of instruction. A plan that employs only online coursework for instruction in responsible conduct of research will not be considered acceptable, except in special instances of short-term training programs (see below), or unusual and well-justified circumstances.

2. Subject Matter: While there are no specific curricular requirements for instruction in responsible conduct of research, the following topics have been incorporated into most acceptable plans for such instruction:

   a. conflict of interest – personal, professional, and financial
   b. policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
   c. mentor/mentee responsibilities and relationships
   d. collaborative research including collaborations with industry
   e. peer review
   f. data acquisition and laboratory tools; management, sharing and ownership
   g. research misconduct and policies for handling misconduct
   h. responsible authorship and publication
   i. the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research
Review Criteria: Training in the RCR

- Does the plan satisfactorily address the format of instruction, e.g. lectures, coursework, and/or real-time discussion groups?

- Do plans include a sufficiently broad selection of subject matter, such as conflict of interest, authorship, data management, human subjects and animal use, laboratory safety?

- Do the plans adequately describe the role of the sponsor/mentor or other faculty involvement in the candidate's instruction?

- Does the plan meet the minimum requirements for RCR, i.e., eight contact hours of instruction every four years?

- Plans and past record will be rated as acceptable or unacceptable, and the summary statement will provide the consensus rating of the review committee.

- Applications rated unacceptable will not be funded until the applicant provides an acceptable, revised plan.
The Research Plan

• Specific Aims

• Research Strategy
  • Significance
  • Innovation
  • Approach
Specific Aims

• See Webinar: “Specific Aims: Dos and Don’ts”

• This is your chance to get the reviewers’ attention!

• Paragraphs
  ▪ The topic is important
  ▪ There is a knowledge gap
  ▪ You have a hypothesis
  ▪ You are the one to fill the knowledge gap
  ▪ “Upon successful completion of the proposed Aims, . . . “
  ▪ Be clear!

• Fatal Flaw: Aims should be independent (one should not depend on the success of another)
Research Strategy

• Significance, Innovation and Approach
  ▪ Other talks in this series will discuss research strategy
  ▪ Page limit includes research strategy + candidate background + goals/objectives + career development plan = 12 pages

• Fine balance between
  ▪ “innovative” and “safe” in the K-award
  ▪ Too much or too little work proposed

• Consider . . .
  ▪ Small budget so what can you leverage?
  ▪ How will this form the basis of your career?
  ▪ Where will you be at completion of the Aims?
  ▪ What’s the next step?
Research Strategy (cont)

- Be clear! Explain why!
- Yes, you need preliminary data
- Demonstrate feasibility
- Include benchmarks/timeline
- Include limitations/potential problems with alternative strategies: “if x, than y”
Review Criteria: Research

• Are the proposed research question, design, and methodology of significant scientific and technical merit?

• Is the research plan relevant to the candidate's research career objectives?

• Is the research plan appropriate to the stage of research development and as a vehicle for developing the research skills described in the career development plan?

• If applicable, are there adequate plans for data and safety monitoring of clinical trials?
Letters of Reference

• 3-5 established scientists
• Plan ahead!
• Provide them a draft or some writing points
  ▪ Write to the candidate criteria
• Provide them instructions
Letters of Support

• Mentors and Advisory Committee or Collaborators
  ▪ 6 pages total
  ▪ A good portion of the review is about your mentor(s) so this is where you will sell the mentoring team!

• Components
  ▪ The Mentor: their prior research, funding, training record (particularly other K-awards)
  ▪ You: their support for your career development, how you will be evaluated, plan for transition to independence, why are they ideal for your team?

• You should write the first draft to make sure all of the information is there.
Review Criteria: Mentors

- Are the mentor's research qualifications in the area of the proposed research appropriate?

- Do(es) the mentor(s) adequately address the candidate's potential and his/her strengths and areas needing improvement? Is there adequate description of the quality and extent of the mentor's proposed role in providing guidance and advice to the candidate?

- Is the mentor's description of the elements of the research career development activities, including formal course work adequate?

- Is there evidence of the mentor's, consultant's, collaborator's previous experience in fostering the development of independent investigators?

- Is there evidence of previous research productivity and peer-reviewed support?

- Is active/pending support for the proposed research project appropriate and adequate?

- Are there adequate plans for monitoring and evaluating the career development awardee's progress toward independence?
Letter of Institutional Support

- Chief of Medicine or Division Director
- You will have a job, independent of the K-award
- You will have protected time (at least 75%)
- You are amazing!

- Again, write the points out for them and consider writing a draft.
Description of Research Environment

• Demonstrate a strong, well established research program related to your area of interest
• Specific programs relevant to your research and career
  ▪ Info about the clinics where patients will be recruited
  ▪ Core services that you will use
• University/Division
• Can add additional resources to your “Facilities and Resources” document
Review Criteria: Environment/Institutional Commitment

- Is there clear commitment of the sponsoring institution to ensure that the required minimum of the candidate's effort will be devoted directly to the research described in the application, with the remaining percent effort being devoted to an appropriate balance of research, teaching, administrative, and clinical responsibilities?

- Is the institutional commitment to the career development of the candidate appropriately strong?

- Are the research facilities, resources and training opportunities, including faculty capable of productive collaboration with the candidate adequate and appropriate?

- Is the environment for scientific and professional development of the candidate of high quality?

- Is there assurance that the institution intends the candidate to be an integral part of its research program?
More documents: areas to expand and support your application

• Your Biosketch: use the personal statement!
  ▪ summarize your application
  ▪ How will the K-award lead to you becoming an independent investigator?

• Mentor/collaborator biosketches
  ▪ Biosketches are limited to 4 pages and 15 relevant publications.
  ▪ Make sure their biosketch is personalized for your grant

• Facilities and resources
• Budget Justification
• Appendix
And More Documents!

- Cover letter
- Project summary (abstract)
- Project narrative (public health statement)
- Mentor Other Support pages
- Equipment
- Research and related performance sites
- Resource sharing plan
- Consortium/contractual agreements
- Human subjects and/or vertebrate animal and/or selected agents research
Submitted! Now what?

• Administrative review
• Major updates? Send an update letter.
  ▪ Due 30 days before study section.
• Committee review
• Impact Score available
• Summary sheets available 4-6 weeks after committee review
• Request for Just in Time documents
• Advisory council review

http://grants.nih.gov/grants/grants_process.htm
### What’s the pay line?

<table>
<thead>
<tr>
<th>About Us</th>
<th>Funding Plan Fiscal Year 2014</th>
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<tbody>
<tr>
<td>FY 2014</td>
<td>Updated March 13, 2014</td>
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<tr>
<td>FY 2013</td>
<td>NIAMS FY 2014 Operating Level: $520,053,000</td>
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<tr>
<td>FY 2012</td>
<td>The NIAMS is operating under the Consolidated Appropriations Act (Omnibus) of 2014. The funding plan below for research and training grants represents the most current information as of the date cited above; however, many factors occurring throughout the fiscal year can affect the operating policies, thus they are subject to change. For clarification it is always best to check with an appropriate Institute official.</td>
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<tr>
<td>FY 2011</td>
<td><strong>Research Project Grants (RPGs)</strong></td>
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<td>FY 2010</td>
<td><strong>Noncompeting RPGs:</strong></td>
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<tr>
<td>FY 2009</td>
<td>In accordance with current NIH FY 2014 fiscal policy, some noncompeting awards will reflect a reduction from the amount recommended on the previous Notice of Grant Award.</td>
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<td>FY 2008</td>
<td>For noncompeting continuations of grants first awarded or competitively renewed prior to FY 2013, this reduction will be approximately 2 percent. No reduction will be applied to noncompeting continuations of grants first awarded or competitively renewed in FY 2013. Out-year commitments will remain unchanged.</td>
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<td>FY 2007</td>
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#### FY 2013

**Research Career Awards**

- K01/K02/K08/K25 applications will be paid through the priority score of 30.
- K23/24 applications will be paid through the priority score of 29.
- K99 applications will be paid through the priority score of 17.

#### FY 2014

**Research Career Awards**

- K01/K08/K25 applications will be paid through the priority score 26.
- K23/24 applications will be paid through the priority score 30.
- K99 applications will be paid through the priority score 24.

Not funded? 😞
Writing the Revision

• It’s not just about the science, you need to demonstrate progression in your career as well.
• Introduction to the Resubmission is REALLY important.
• Listen to the reviewers and address their concerns!
• Track changes
Getting started . . .

• First, build you!
• Demonstrate a commitment to research
• Find a topic you love
• Identify a mentor/mentoring team
• Get to know your resources
• Talk to your division chief
• Get to know the SF424 Application Guide
  ▪ Set up an ERA commons account

https://public.era.nih.gov/commons
Develop a Central Theme

- What will your career look like?
- List questions of interest: these should be discrete, specific, and answerable
- Propose hypotheses and potential studies to address them
- How would such studies help you lay a foundation for your career?
- Studies to stick with:
  - Novel
  - Fills a knowledge gap
  - Definitive (not a pilot study)
  - Feasible
  - Low cost
    - Can you leverage available resources?
  - Rigorous
  - Skill-building
  - Should also make you independent from your mentor(s)
Starting to put it all together

- Get examples!
- Check out K-clubs (or grant-writing resources at your institution)
- Contact your grant manager/grants office
- Contact your SRO with questions
General Tips for Success

• A master checklist is a must
• Start early, write often, talk a lot
• Aims are critical
• Make it simple and clear
• Get others to review your grant.
• The reviewers are right
• Know the directions inside and out
• Know the criteria and write to them

• *Write, rewrite, rewrite, rewrite, rewrite*. . .
• *Review, review, review, review everything!*
Resources

• Your mentors, your division chief, your institution, your peers
• The SF424 Application Guide
• ACR Webinars
• Your Scientific Review Officer and NIH Administrative Staff
• K-Kiosk http://grants.nih.gov/training/careerdevelopmentawards.htm
All About Grants: Tutorials and Samples

All About Grants helps investigators plan and write grant applications and manage their awards. Help us improve our outreach to you by emailing deaweb@niaid.nih.gov.

All Investigators

Strategy for NIH Funding
Get sound guidance and a solid strategy for RO1 applications and grants in the Strategy for NIH Funding.

More Tutorials in Topic Areas
- New Investigator Guide to NIH Funding
- Guidance for Preparing a Multiproject Research Application
- How to Write an Application Involving Research Animals
- NIAD Human Subjects Application and Grant Handbook and Checklists for Human Subjects
- Advice on Research Training and Career Awards
- Advice Presentations for SBIR and STTR
- Grants Policy and Management: Training for Foreign Investigators

New Investigators

Resources by Career Stage
Find resources for your career stage.

- Advice on Research Training and Career Awards—get advice on fellowships, career awards, institutional T32 training grants, and supplements
  - Training and Career portal—find information for early career stages.
- New and Early-Stage Investigators portal—find out which support types are appropriate for you.
  - New Investigator Guide to NIH Funding—learn the basics about NIH and how to qualify as a new PI of an independent grant.
  - Checklist for New Investigators

Application Tools

Sample Applications
- Samples and Examples—find examples of whole and sections of applications
Thank you for attending today!
Acknowledgements

• Early Career Investigator Subcommittee
• John Peyman, PhD
• Sarah Zirkle
• Elizabeth Karlson, MD
• Louis Bridges, MD PhD
Questions?