Applying for an NIH Career Development Award

Rochelle P. Walensky, MD, MPH
Associate Professor of Medicine
Harvard Medical School

Divisions of Infectious Disease
Massachusetts General Hospital
Brigham and Women’s Hospital
With appreciation:

Ingrid V. Bassett, MD, MPH
Kenneth A. Freedberg, MD, MSc
What is a K Award?

• NIH Career Development Award (CDA) providing up to 5 years of investigator support

• Types:
  – K01 Mentored Research Scientist CDA
  – K08 Mentored Clinical Scientist CDA
  – K23 Mentored Patient-Oriented Research CDA
  – K25 Mentored Quantitative Research CDA

• Career Award Wizard:
  http://grants.nih.gov/training/careerdevelopmentawards.htm
Who should apply?

- Do you want to do research?
- As the majority of your career?
- The path to a research career
  
  T32 $\longrightarrow$ K Award $\longrightarrow$ R01
Average Age of New Investigator at Initial R01 Equivalent Award

- MD-PhD: $y = 0.2102x + 34.467$, $R^2 = 0.9835$
- MD: $y = 0.1743x + 36.869$, $R^2 = 0.8925$

Graph showing the average age of new investigators at the time of their initial R01 equivalent award from 1970 to 2004, with trends for MD-PhD and MD degree holders.
NIH Grant Cycle

http://funding.niaid.nih.gov/researchfunding/grant/cycle/pages/default.aspx
3 Major Changes from the Past

- Electronic submission
- One resubmission (instead of 2)
- 12-page research plan (from 25-page)
When to apply

• Do the math and apply early: If it takes two cycles to get funded, the minimum time from 1\textsuperscript{st} submission to funding is generally 18 months.

• When you (or your mentor) has applicable preliminary data and abstract presentations.

• Long before you absolutely need the money.
# Deadlines and Dates to Remember

<table>
<thead>
<tr>
<th></th>
<th>Cycle 1</th>
<th>Cycle 2</th>
<th>Cycle 3</th>
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<tbody>
<tr>
<td><strong>Due Dates</strong></td>
<td>12-Feb</td>
<td>12-Jun</td>
<td>12-Oct</td>
</tr>
<tr>
<td><strong>AIDS-related Due Dates</strong></td>
<td>7-May</td>
<td>7-Sept</td>
<td>7-Jan</td>
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<tr>
<td><strong>Scientific Merit Review</strong></td>
<td>June-July</td>
<td>Oct-Nov</td>
<td>Feb-Mar</td>
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<td><strong>Advisory Council Review</strong></td>
<td>Sep-Oct</td>
<td>Jan-Feb</td>
<td>May-Jun</td>
</tr>
<tr>
<td><strong>Earliest Project Date</strong></td>
<td>Dec</td>
<td>April</td>
<td>July</td>
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*Revised applications are submitted one month later than standard deadlines, except in AIDS*
## An Example

<table>
<thead>
<tr>
<th>T32 Fellow:</th>
<th>2&lt;sup&gt;nd&lt;/sup&gt; K planning</th>
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<table>
<thead>
<tr>
<th>1&lt;sup&gt;st&lt;/sup&gt; K planning</th>
<th>2&lt;sup&gt;nd&lt;/sup&gt; K submission</th>
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<tbody>
<tr>
<td>Started 09/2005</td>
<td>Submitted 09/01/06</td>
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<tr>
<th>1&lt;sup&gt;st&lt;/sup&gt; K submission</th>
<th>2&lt;sup&gt;nd&lt;/sup&gt; K score</th>
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<tbody>
<tr>
<td>Submitted 01/02/06</td>
<td>Received 01/2007</td>
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<table>
<thead>
<tr>
<th>1&lt;sup&gt;st&lt;/sup&gt; K score</th>
<th>K01 Started: 07/01/07</th>
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<tbody>
<tr>
<td>Received 05/2006</td>
<td></td>
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</table>

K01 Started: 07/01/07
Which institute?

- Money options
- Think broadly
- Work with your mentor
- Consider funding lines (and funding details) at alternatively applicable institutes
- Consider dual agencies
- Look at FY research missions of applicable institutes
Which Institute?

Where should I start?  
Early Steps

- Identify a mentor(s) and discuss if s/he is willing to take on this role
- Develop a detailed timeline. Stick to it!
- Carefully review the SF 424 instructions
  - Follow the Career Dev Award (CDA) instructions
- Review several successful K applications (*keep in mind NEW format starting in 2010*)
- Review several summary statements
  - You learn more from the unsuccessful applications
- Identify your contact in grants management office
NIH Research RePORTER
http://projectreporter.nih.gov/reporter.cfm
What makes a good mentor?

Ideally...

- NIH-funded
- Has mentored other fellows though a K process
- Can highlight prior research trainees who have successfully transitioned to independent research (track record)
- Co-mentor option
Who needs to be involved?

- Mentor and co-mentor
  - Provide drafts early in the process and according to agreed upon timeline
- Biostatistician
- Grants Management
  - Check with your grants mgmt office re: timeline for sign off
- Chairman/Institutional support
  - Must be signed by person authorized to commit the institution to agreements and assurances
Obtaining Biostatistical Support

• What types of support might I need?
  – sample sizes and power calculations
  – anticipated statistical analysis (clinical or basic research)

• When do I need to request support?
  – Min. of 8 weeks prior to grant submission

• Where can I obtain support?
  – Clinical Research Program (“boilerplate”)
  – Center for AIDS Research (CFAR)
  – Discuss with your mentor
A Successful K

- $700,000 of taxpayer money
  - The candidate
  - The mentor/team
  - The project

- Is it worth it?
What are the components?
Candidate & Research Plan (12 pgs!)

• Candidate Information (~4 pages)
• Research Strategy (~8 pages)
  – + 1 additional page for Specific Aims

• A major change from 25 pages, made January 2010
Candidate Piece Components (4-5 pgs)

- Candidate’s Background
- Career Goals and Objectives
- Career Development/Training Activities
- Training in the Responsible Conduct of Research
Candidate Piece Components

- DETAILED plan of courses: course numbers, who is teaching them, their expertise and national/international recognition
- DETAILED plan for meeting with mentors: twice weekly, time/dates of intended meetings
- Scientific Advisory Board
## Major Changes to Research Plan

<table>
<thead>
<tr>
<th>Previous</th>
<th>Restructured</th>
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<tbody>
<tr>
<td>1. Intro to Application (resubmissions only)</td>
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<tr>
<td>2. Specific Aims</td>
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</tr>
<tr>
<td>4. Prelim studies</td>
<td>a. Significance</td>
</tr>
<tr>
<td>5. Research Design</td>
<td>b. Innovation</td>
</tr>
<tr>
<td></td>
<td>c. Approach (inc prelim studies)</td>
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</table>
Research Strategy

- Specific Aims (~1 page)
- Research Strategy (~8 pages)
  - Significance
  - Innovation
  - Approach (includes preliminary studies)
- Includes tables, graphs, figures, etc
Specific Aims (~1 page)

• Brief paragraph about the importance of the work (NOT the abstract verbatim)
• List of the specific aims
• Description of how this research meets the research priorities of the intended agency and the impact the results will have on research field
• Description of how the candidate/mentor team are well-poised to complete the research and transition the mentee to independent funding
Research Strategy: Significance

A. Significance (~1/2-1 page)
   • Importance of problem or barrier to progress in field that project addresses
   • How project will improve scientific knowledge and how results will change the field
   • One of 5 major review criteria
Research Strategy: Innovation

B. Innovation (~1/2-1 page)

- How application challenges current research or clinical paradigms
- Describe novel methods or concepts
- Explain improvements or new applications of concepts, methods, or interventions
- One of 5 major review criteria
Research Strategy: Approach

C1. Approach (~6-7 pages total)

Preliminary studies

- Work in progress with preliminary data toward the specific aims
- Abstracts submitted, accepted
- Manuscripts under review (on this or other topics)
- Work of your mentors that demonstrates the feasibility of your project
C2. More on Approach

Study design

• Most important section
• Thoughtful design of how the aims will be executed. What if you hit a roadblock? If the 1st aim fails? If your enrollment fails?
• Detailed list of deliverables: proposed titles? Meetings/dates for abstract submissions? Manuscript submissions
• Timeline for when each aim/manuscript will be complete
Scoring

• Completed by the Scientific Merit Review (Member lists are available online)
• Scale of 1-9: A raw score of 1 is the best possible (9 the worst)
• Judged on 5 core review criteria with brief summary of strengths/weakness of each:
  – Significance
  – Investigators
  – Innovation
  – Approach
  – Environment
  – OVERALL IMPACT
READ THIS: Definitions of Criteria & Considerations for K Critiques
http://grants.nih.gov/grants/peer/critiques/k.htm#k_overall

- Overall impact
- Candidate
- Career Development Plan/Career Goals/Plan to provide mentoring
- Research plan
- Mentors, consultants, collaborators
- Environment and institutional commitment
- Protection of human subjects
But, I wish that were it…
It’s not

- Do not forget or underestimate the administrative paperwork!
- This will take you more time than you think (and maybe even more time than writing the grant)
**RESEARCH CAREER DEVELOPMENT AWARD TABLE OF CONTENTS (Substitute Page)**

### Letters of Reference* (attach unopened references to the Face Page)

<table>
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<tr>
<th>Section</th>
<th>Page Numbers</th>
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<tbody>
<tr>
<td>Face Page (Form Page 1)</td>
<td>1</td>
</tr>
<tr>
<td>Description, Project/Performance Sites, Senior/Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells (Form Page 2)</td>
<td>2</td>
</tr>
<tr>
<td>Table of Contents (this CDA Substitute Form Page 3)</td>
<td></td>
</tr>
<tr>
<td>Budget for Entire Proposed Period of Support (Form Page 5)</td>
<td></td>
</tr>
<tr>
<td>Biographical Sketches (Candidate, Mentor[s],* Key Personnel and Other Significant Contributors* —Biographical Sketch Format page) (Not to exceed four pages)</td>
<td></td>
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<tr>
<td>Other Support Pages (for mentor(s)only)</td>
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<tr>
<td>Resources (Resources Format page)</td>
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### Career Development Plan

#### The Candidate

- Candidate’s Background
- Career Goals and Objectives: Scientific Biography
- Career Development/Training Activities during Award Period
- Training in the Responsible Conduct of Research

#### Statements by Mentor, Co-Mentor(s),* Consultant(s),* and Contributor(s)*

### Environment and Institutional Commitment to Candidate

- Description of Institutional Environment

### Institutional Commitment to Candidate’s Research Career Development

### Research Plan

1. Introduction to Resubmission Application* (Not to exceed 3 pages)
2. Specific Aims
3. Background and Significance
4. Preliminary Studies/Progress Report
5. Research Design and Methods

*Page Numbers:*
Administrative Paperwork

- Electronic submission—click “Apply for Grant Electronically” from RFA to find electronic forms
- Critical instructions start on page 36
- Early submission (2 weeks prior to grant deadline) to grants management!
What Are the Components?
Administrative Paperwork

- Face Page (SF 424 R&R)
- Project/Performance Site
- Abstract & Narrative
- Facilities & Other Resources (institutional)
- Key Personnel
- Biosketches
- Modified Other Support (sponsor[s])
- Budget & Justification
- Cover Page & Checklist Page
Other Components?
Support Letters

• Three letters of reference
  – NOT directly involved in the application
  – Familiar with your qualifications, training, interests
  – Should address competence and potential
  – Referees upload letters via eRA portal
• Letters of support by Sponsor and Co-sponsor
• Institutional Commitment
  – Dean or chairman of the department
• Scientific Advisory Board
  - 3-5 people who will meet yearly to assist you in monitoring your progress
Support Letters

• Among the only pieces of the application that you cannot do last minute. REQUEST EARLY! (And nicely)
• Dated in close proximity to application deadline.
• Do not be put off if you are asked to draft these, especially for consultants and contributors. In fact, you should offer!
K Writing Timeline

4 months prior

• Identify sponsor/co-sponsor
• Make timeline and share with sponsor
• Draft specific aims
• Identify individuals for letters of support
• Register on eRA commons
• Visit Grants.gov to download instructions and appropriate electronic grant application
Timeline continued

3 months prior

- Request letters of support – references/sponsor(s)/institutional commitment
- 1\textsuperscript{st} draft – research plan/candidate statement/abstract
- Identify advisory board and request letters
- Request all required biosketches / other support
- Determine required biostatistical support and request assistance
Timeline continued

2 months prior

• Circulate 1\textsuperscript{st} draft research plan/statement for feedback
• Revise research plan/statement and circulate 2\textsuperscript{nd} draft
• Follow up on all requested letters, biosketches, other support
• Complete all administrative paperwork and budget
Timeline continued

1 month prior

- Send all administrative paperwork to grants mgmt (3 weeks prior)
- Consider sending out to an external reviewer for comments
- Finalize research plan
- Check all formatting, numbers, etc.
- Make edits requested by grants management
- The last week – diminishing returns? No!
Timeline continued

Submitting the grant

• Electronic submission using Grants.gov downloadable forms
• Include a cover letter (list names/addresses of recommenders—see instructions)
• Grants management makes final submission
• Follow up with all collaborators, mentors, letter writers, thanking them for their contribution
Once submitted:

- Follow progress on eRA Commons (https://commons.era.nih.gov/commons/)
- Receive your score
- Stay in touch with your project officer, get feedback before the summary statement is available!

- Plans for resubmission: 1 page introduction
Other Helpful Resources

K Kiosk (Career Award Wizard and Links to Awards):
grants.nih.gov/training/careerdevelopmentawards.htm

SF 424 R&R Instructions, including human subjects:
grants.nih.gov/grants/funding/424/index.htm

Details of New Sections and Page Limits:
enhancing-peer-review.nih.gov/docs/application_changes.pdf

NIH Office of Extramural Research (OER) Home Page
grants.nih.gov/grants/oer.htm
Take-home messages

• This is a long process to which you must be committed
• Is research your long-term plan?
• Allow adequate time—especially for things that are out of your control (biostatistical support, letters)
• Pay attention to details
• Review instructions continuously during your preparation