Applying for an NIH Career Development Award

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With appreciation:

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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:

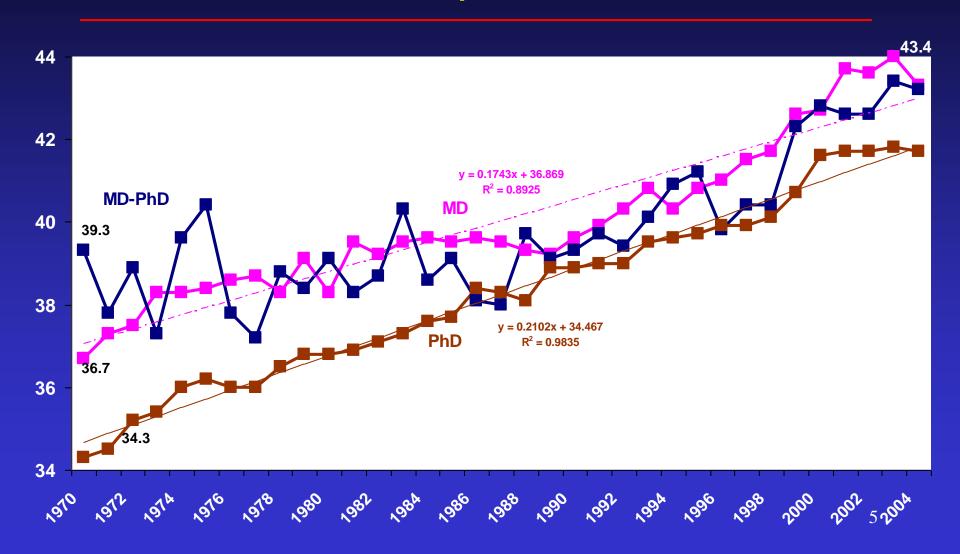
http://grants.nih.gov/training/careerdevelopmentawards.htm

Who should apply?

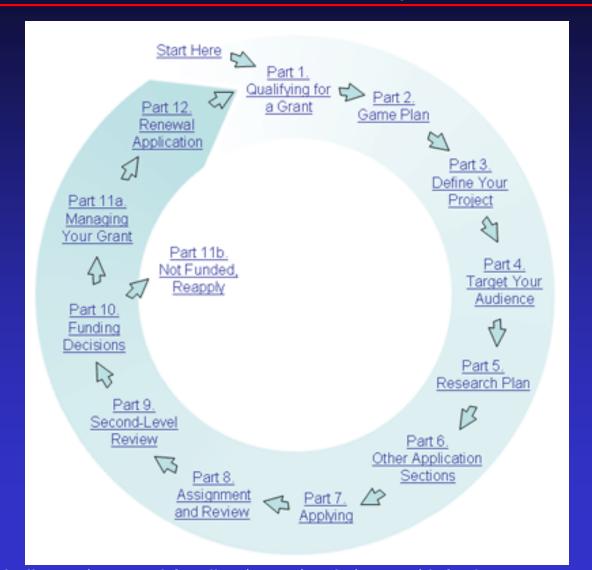
- Do you want to do research?
- As the majority of your career?
- The path to a research career

T32 → K Award → R01

Average Age of New Investigator at Initial R01 Equivalent Award



NIH Grant Cycle



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 1st 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

| | Cycle 1 | Cycle 2 | Cycle 3 |
|-------------------------|-----------|-----------|------------|
| Due Dates* | 12-Feb | 12-Jun | 12-Oct |
| AIDS-related Due Dates | 7-May | 7-Sept | 7-Jan |
| Scientific Merit Review | June-July | Oct-Nov | Feb - Mar |
| Advisory Council Review | Sep - Oct | Jan - Feb | May - June |
| Earliest Project Date | Dec | April | July |

^{*}Revised applications are submitted one month later than standard deadlines, except in AIDS

An Example

| T32 Fellow: | 2 nd K planning |
|----------------------------|------------------------------|
| 7/2005 — 6/2007 | Started 05/2006 |
| 1 st K planning | 2 nd K submission |
| Started 09/2005 | Submitted 09/01/06 |
| 1st K submission | 2 nd K score |
| Submitted 01/02/06 | Received 01/2007 |
| 1st K score | K01 Started: 07/01/07 |
| Received 05/2006 | |

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

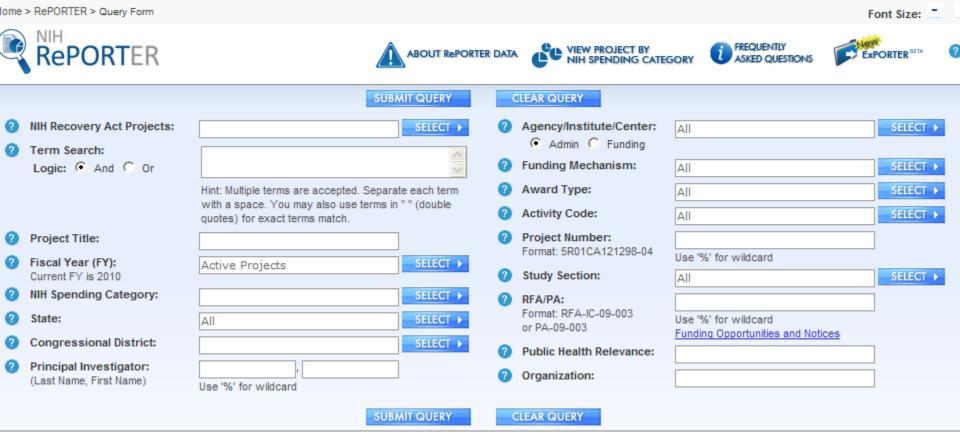
Which Institute?

- National Institute of Allergy and Infectious Diseases (NIAID) (http://www.niaid.nih.gov/)
- National Institute on Alcohol Abuse and Alcoholism (NIAAA), (http://www.niaaa.nih.gov/)
- National Cancer Institute (NCI) (http://www.nci.nih.gov/)
- National Institute of Child Health and Human Development (NICHD), (http://www.nichd.nih.gov/)
- National Institute on Drug Abuse (NIDA), (http://www.nida.nih.gov/)
- National Institute of Mental Health (NIMH), (http://www.nimh.nih.gov/)

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 <u>agreed upon</u> 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

| Previous | Restructured |
|--|--|
| 1. Intro to Application (resubmissions only) | 1. Intro to Application (resubmissions only) |
| 2. Specific Aims | 2. Specific Aims |
| 3. Background & Significance | 3. Research Strategya. Significance |
| 4. Prelim studies | b. Innovation |
| 5. Research Design | c. Approach (inc prelim studies) |

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

Research Strategy: Approach con't

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 on line)
- 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)

Old Version: Your TOC will look different

| CDA TOC Substitute Page | Candidate (Last, first, middle): | |
|---|--|----|
| Use this Table of Contents for Research (| Career Development Awards. Include candidate's name on each page. | _ |
| RESEARCH CAREER D | DEVELOPMENT AWARD TABLE OF CONTENTS (Substitute Page) | |
| | Page Number | rs |
| Letters of Reference* (attach unopened re- | ferences to the Face Page) | |
| Basic Administrative Data | | |
| Face Page (Form Page 1) | | 1 |
| Description, Project/Performance Sites, Senior (Form Page 2) | /Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells | 2 |
| Table of Contents (this CDA Substitute Form P | age 3) | _ |
| | Form Page 5) | _ |
| Biographical Sketches (Candidate, Mentor[s],* —Biographical Sketch Format page) (Not to | Key Personnel and Other Significant Contributors* exceed four pages) | _ |
| Other Support Pages (for mentor(s)only) | | _ |
| Resources (Resources Format page) | | _ |
| Career Development Plan | | |
| The Candidate | | |
| Candidate's Background | ······ | _ |
| Career Goals and Objectives: Scientific Bio | graphy(Items included in 25 page limit) | |
| Career Development/Training Activities dur | ing Award Period | _ |
| Training in the Responsible Conduct of Res | search | |
| Statements by Mentor, Co-Mentor(s),* Cons | ultant(s),* and Contributor(s)* | |
| Environment and Institutional Commitment | to Candidate | |
| Description of Institutional Environment | | _ |
| Institutional Commitment to Candidate's Re | search Career Development | _ |
| Research Plan | | |
| • | * (Not to exceed 3 pages) | |
| • | ······································ | _ |
| | (Items 2-5 included in 25 page limit) | _ |
| 4. Preliminary Studies/Progress Report | | _ |
| | | |

Administrative Paperwork

- Electronic submission—click "Apply for Grant Electronically" from RFA to find electronic forms
- Instructions for filling in forms available at: http://grants.nih.gov/grants/funding/424/SF424_ RR_Guide_General_Adobe_VerB.pdf
- 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

3 months prior

- Request letters of support –
 references/sponsor(s)/ institutional commitment
- 1st 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

2 months prior

- Circulate 1st draft research plan/statement for feedback
- Revise research plan/statement and circulate 2nd draft
- Follow up on all requested letters, biosketches, other support
- Complete all administrative paperwork and budget

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!

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