Writing a Mentored Grant

Karen Teff, Ph.D.

Monell Chemical Senses Center

Co-Director, Clinical and Translational Research Center

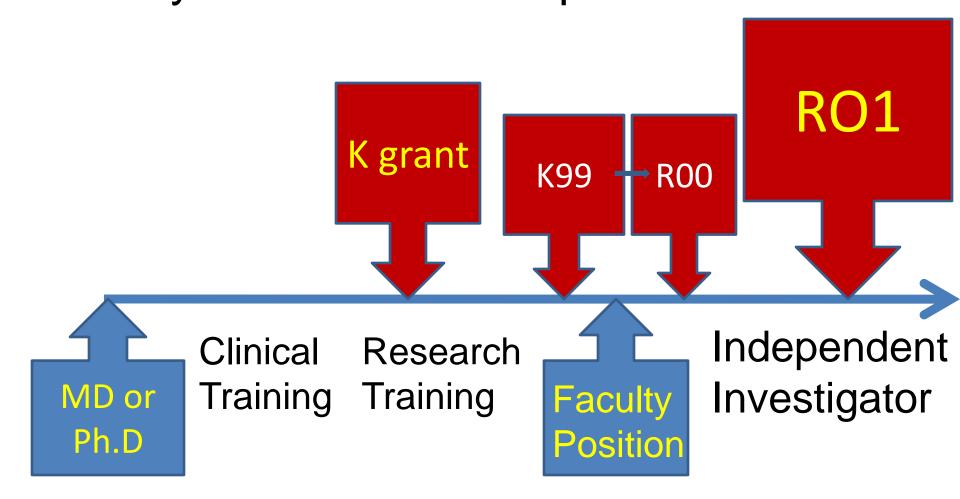
Steven Albelda, M.D. Department of Medicine

Ron Rubenstein, M.D., Ph.D. Department of Pediatrics

Getting Started

- Read the Program Announcement of the grant mechanism
- Understand the components of the grant you need to address: <u>Application receipt dates</u>, <u>Deadlines</u>, <u>Review dates</u>, <u>Eligibility</u>, <u>Provisions</u>, Review Criteria, <u>Policy requirements</u>, <u>Contact information</u>
- Decide on your research strategy
 - Hypothesis/experiments

Pathway to Scientific Independence



Types of Mentored Career Development Awards

 There are a number of different mentored K awards that individuals with a research or health professional doctorate should consider.

 Most of these awards support individuals after they have completed training and are transitioning to a faculty position.

General Tips on Mentored K Awards

- The intent of the mentored K award.
 - To help promising new investigators achieve research <u>independence</u> (i.e., to compete successfully for *RO1 funding*).
 - Therefore, preparing for the R01 grant application you will submit at the end of the K award should be the *organizing principle* of the K grant application.

Different K grants

 Training grants (K grants differ between institutes, check PA!!!)

KO1: Ph.D. (specific to Institute)

K08: Clinical Degree

K23: Patient-Oriented Research

K99/R100: (Only training grant doesn't

require citizenship)

Key Features of Mentored K Awards

- 3 5 years in length
- Provide substantial salary support but limited research funding.
- Contain both a training plan and a research plan.
- Includes a team of mentors, co-mentors, advisors, etc.
- Goal: transition to research "independence".

Funds associated with K grants

Amount of Funding	K01	K08	K23
per year			
Salary	\$50K -	\$75K -	\$75K -
Support	\$150K	\$105K	\$180K
	(\$75K)	(\$75K)	(\$75K)
Research/ \$20K -		\$20K -	\$25K -
Training	\$50K	\$90K	\$50K
	(\$25K)	(\$25K)	(\$25K)

Program Officers: When to contact

- Find contact info in PA
- When to contact
 - Prior to grant submission contact early:
 - Is your research question of interest to the Institute?
 - If it isn't, you need to find a more appropriate institute (depends on primary outcome variables) or re-think your question
 - Do not feel uncomfortable about phoning
 - Do homework first, Read PA,
 - Email first, send a 1 page concept page or specific aims, set up time to talk
 - After you receive summary statement: feedback

Components of Mentored grants:

K grants: Provide further training to transition into independence

- Candidate
- Career Development Plan
- Research Plan
- Mentors, Co-Mentors and Consultants
- Environment and Institutional Commitment
- 3 letters of recommendation

Candidate

- Potential to develop as an outstanding independent researcher
- Likelihood that the career development plan will contribute substantially to the scientific development of the candidate
- Your publications, peer reviewed data based
 - how many and what journals
 - abstracts, review articles, chapters no weight
- Do you show evidence of a long term commitment to a research career?
- Letters of References

Find the right mentor

The most critical component of your first research experience is a good mentor

A good mentor is not necessarily:

- the head of your lab
- the 'nice guy' that will talk to you
- just one person

Characteristics of a Good Mentor

Does your mentor have NIH funding?

 Does your mentor have an active research program going on?

- Does your mentor have numerous recent publications?
- Has your mentor mentored other people who have been successful?

General Tips on Mentored K Awards (cont'd)

- Develop a career development training plan that is uniquely suited to you.
 - Given your previous training and research experience, and your short- and long-term career goals, propose a mix of didactic training and "hands- on" research experience that make perfect sense for you (and only you).
 - Degree-granting programs (e.g., MPH, MAS) are appropriate for candidates with little or no previous formal training in research, but even these programs should be "customized" whenever possible.

General Tips on Mentored K Awards (cont'd)

- Make a compelling argument why <u>you</u> need a K award
 - Explain <u>exactly</u> how additional training and mentored research experience will enable you to compete successfully for R01 funding.
 - Be specific: give concrete examples of areas where you need additional training or experience in order to conduct the proposed research or areas where you are deficient that are directly related to your research career goals.

Training Plan

- Career goals
- Expand scientific skill set (methods, preliminary data and publications)
- Mentoring team: frequency of meeting etc
- Set you up for next level of funding
- When you expect to publish your papers, when you will submit RO1, (what RO1 would be on)
- Training plan must match career goals AND
- Specific aims

Career Goals and Objectives

- Describe the specific areas where you have deficiencies (e.g., primary data collection, biostatistics, qualitative research methods).
- Example: I have made progress in developing my clinical research skills, but there are three important areas where I require additional training, mentoring, and experience: (1) multi-disciplinary collaboration with clinical and basic scientists, (2) the design and implementation of prospective study design with involvement in the IPFnet, and (3) advanced study design and biostatistical methodology. In the following section, I present a detailed career development plan designed to enable me to acquire the additional training and mentored research experience I need to address these deficiencies and compete successfully for R01 funding, thereby achieving independence as a clinical investigator.

Specific Aims Page

- Most important page of the grant
- In one page, you need to convince someone about why this is important and give them an overview of what you are going to do
- Explain why the question you are asking is important
- After reading this one page, the reviewer should know what you want to do

Specific Aims

- State overall goal of grant
- State hypothesis for each specific aim (try to limit to 3)
- Hypothesis:
 - -Make sure your experiments are really addressing the hypothesis you have written
 - -Don't use ambiguous words

RESEARCH STRATEGY: getting started (one strategy)

- Start with writing out experiments
- Create chart of expected outcomes and interpretation of data
- Work out experiments first
- Understand what the experiments are testing
- Need to match up hypotheses and proposed experiments.
- After you do this, then go back and write the specific aims page

Preliminary Data

- Do you have preliminary data for all your aims?
- Can you convince the reviewers that you can do what you are proposing to do
- Does your mentor have experience doing what you are proposing?
- For human studies, can you demonstrate that you can recruit the subject population you are proposing?
- For animal studies, is the model established?

Innovation

- Generate excitement about project and questions being asked
- Are you asking an important scientific question?
 (just because nobody has ever done what you are proposing doesn't mean it is important)

— Is it going to provide information that doesn't exist or is it a variation on a theme?

– Does it have health relevance?

— What is new about you are proposing?

EXPERIMENTAL DESIGN METHODS

 Due to the new page limitations, have to decide what you should put in and what you can leave out. This is tricky.

 If the method is published, then you can refer to the paper. If it isn't, then you have to describe in detail.

STATISTICS AND POWER CALCULATION

 Make sure you describe how you are going to determine significance, what statistical test

 For human and animal studies, you need to do a power calculation to determine your "n"

INTERPRETATION OF RESULTS AND FUTURE DIRECTIONS

 You should always have a section on potential outcomes: what you expect to see and what happens if your hypothesis is wrong. How will you interpret the data if the results are not what you expect?

 Future directions should state where you will go next with these results.

Environment and Institutional Comittment

- Does the environment provide you with the scientific expertise you need to complete the proposed project?
- Does the environment provide you with the equipment and resources you are going to need to complete the proposed project?
- NRSAs and K provide no or limited funds for research.
- You will need a letter from Chair. Is the Institute willing to support you <u>independent</u> of receiving the K

Example of key elements of an Institutional Support Letter from a successful K08 Application

The Department of XXXXX is committed to fostering Dr. XXXX's career. Within the next year, we plan to offer Dr. XXX a promotion to Instructor, **our initial faculty appointment.** This K08 award will allow Dr. XXXX to receive additional formal training in cell and molecular biology, *in vivo* imaging, and advanced immunological analyses while designing and completing a research project.

When we commit to a faculty position, we believe there are a number of key factors that are necessary critical for long-term success. First, if he receives the Mentored Clinical Scientist Research Career Development Award, we will **protect his time** so that he can devote 80% of his effort to scientific investigation with limited clinical responsibilities that are complementary to his research goals. Second, we **will provide the necessary lab space and resources (i.e. technical support)** needed for him to be maximally productive. Third, and perhaps most important, we will assure that he receives the finest **mentoring** possible.

Statement of Support from Mentor

- Key part of the grant that cannot be overlooked
- Allows a much more detailed presentation of the training, evaluation, and mentoring plan.
- Allows discussion of the mentoring committee

Key Elements to Mentor Letter

- Qualifications of Mentor
- List of his trainees and their success
- Details of the specific support provided (i.e. supplies, technical support, infrastructure)
- Details of Mentor's support
- Recommendation of candidate

Key Elements to Mentor Letter: Training/Mentoring Plan

- New Techniques and Skills
- Infrastructure and Intellectual Environment
- Lab Meetings
- Course work and conferences
- Other commitments (limitation on clinical work)
- Mentoring plan
- Mentoring Committee
- Expectations and Benchmarks
- Transition Plan
- Summary of support from key co-mentors

Training in the Responsible Conduct of Research

- Format
- Subject Matter
- Faculty Participation
- Duration
- Frequency
- Not just web based

Time to Review and Funding

- Need to plan your time (6-7 months)
- New grant writers underestimate amount of time
 you will need to redo proposal multiple times
- Allow time for feedback from mentor/colleagues
 > 1 month –otherwise will not get substantial feedback.
- University administration needs 2 weeks for administrative and budget pages
- Try not to get defensive, "listen" to criticisms

Time to Review and Funding

- It takes a long time from time of submission to review and receipt of funds
- Count on two submissions. Most applications don't get funded on first submission
- From beginning to end, this could take up to 2 years

Overview NIH

- You send in your grant: what happens next?
- Center for Scientific Review
- Assignment of grant to Institute (where money comes from) and Study Section (where expertise resides)
- How is this decided?
 - -title, abstract and primary outcome variables

Review Process

- Study section has about 30 people
- 3 people actually read the grant
- Initial scores are given by the 3 reviewers
- Primary reviewer describes grant
- Secondary and tertiary add anything else that hasn't been mentioned.
- Open to discussion. Other committee members are looking at the grant online and may weigh in. Around 15 min allotted to each grant (NRSA or Ks)
- RO1s can be triaged and not discussed at all

Scoring Descriptions

Impact	Score	Descriptor	Strengths/Weaknesses
High Impact	1	Exceptional	Strengths
	2	Outstanding	
	3	Excellent	
Moderate Impact	4	Very Good	
	5	Good	
	6	Satisfactory	
Low Impact	7	Fair	
	8	Marginal	
	9	Poor	Weaknesses

Non-numeric score options: NR = Not Recommended for Further Consideration, DF = Deferred, AB = Abstention, CF = Conflict, NP = Not Present, ND=Not Discussed

Scoring Descriptions

Score	Descriptor	Additional Guidance on Strengths/Weaknesses	
1	Exceptional	Exceptionally strong with essentially no weaknesses	
2	Outstanding	Extremely strong with negligible weaknesses	
3	Excellent	Very strong with only some minor weaknesses	
4	Very Good	Strong but with numerous minor weaknesses	
5	Good	Good Strong but with at least one moderate weakness	
6	Satisfactory Some strengths but also some moderate weaknesses		
7	Fair	Some strengths but with at least one major weakness	
8	Marginal	A few strengths and a few major weaknesses	
9	Poor	Very few strengths and numerous major weaknesses	

Minor Weakness: An easily addressable weakness that does not substantially lessen impact

Moderate Weakness: A weakness that lessens impact **Major Weakness:** A weakness that severely limits impact

Responding to Criticisms

- Read the summary statement carefully
- Try to understand exactly what the reviewers didn't like
- Respond to concerns point by point and indicate where you have made the changes
- Do NOT argue with the reviewers