



BRIGHAM AND
WOMEN'S HOSPITAL
A Teaching Affiliate of Harvard Medical School



BRIGHAM AND
WOMEN'S HOSPITAL

BIOMEDICAL RESEARCH INSTITUTE

CENTER FOR FACULTY DEVELOPMENT AND DIVERSITY

*Office for Minority Careers * Office for Postdoctoral Careers * Office for Women's Careers*

BRI Research Career Development Committee

Grant Writing Workshop

December 8, 2006



RCDC/OPC Fall Seminar Series

- 9/15/06 **Research Resource Open House** – ~30 participating groups
- 10/3/06 **Communicating Effectively** – Thomas Lee, M.D.
- 10/17/06 **Writing Effective Scientific Manuscripts** – Jonathan Borus, M.D.
- 10/17/06 **The Rebirth of Scientific Activism** – Michael Stebbins, Ph.D.
- 10/24/06 **Reviewing Manuscripts** – Caren Solomon, M.D.
- 11/07/06 **Writing Effective Abstracts** – Julie Glowacki, Ph.D.
- 11/21/06 **Demystifying Green Cards & Visa Issues** – Claire Ayer, PIO
- 12/8/06 **Grant Writing Workshop** – various faculty



Planned Events for Spring 2007

Research Communications:

- Writing Manuscripts
- Preparing Scientific Presentations
- Grant Writing & Getting Funded
- English as a Scientific Language

Professional Pathways:

- Preparing for Industry
- Managing A Lab
- Alternative Careers

Center for Faculty Development & Diversity:

- Demystifying Promotions Seminar Series
- Negotiations Seminar
- Women As Leaders in Science and Medicine

Your First Grant

P D Allen MD, PhD

Department of Anesthesia, Perioperative
and Pain Medicine, BWH

Before even starting to write!

- Investigator
 - Are you prepared?
 - Have you completed your training?
 - Is there evidence of your abilities and knowledge?
 - Will your supervisor(s) support the application?
 - Are you eligible?
 - Terminal degree in your field
 - Documentation of eligibility requirements

Before even starting to write

- Institution & Resources
 - Is there a commitment to you and your work?
 - Time
 - Lab space
 - Office space
 - Additional research support (first grants are almost never sufficient to do the work proposed)
 - Institution
 - Mentor
 - Collaborators

Before even starting to write

- Investigator Qualifications
- Institutional Commitment
- Resources
- Your Future Goals
- Be sure you understand these and have evidence to support each of them. In most cases, these issues are as important as the research plan for first grants and should be addressed in the appropriate part of the application.

The basic principles of grantsmanship apply:

- What is the project proposed?
- Why is it important?
 - Make it clear that you're proposing what **should** be done, not only what you can do easily.
 - KNOW YOUR FIELD!
 - <http://www.countway.harvard.edu>
- Why should you be the one to do the project?

The basic principles of grantsmanship apply:

- The potential funding organization/mechanism should “match” the investigator, the study and the environment.
- If you have to work to make your application fit the Grant Announcement Description, you probably shouldn't apply for that grant!

The basic principles of grantsmanship apply:

- The potential funding organization/mechanism should “match” the **investigator**, the study and the environment.
 - Fellowship grant for Fellowship training
 - New Investigator grant for a new investigator
 - Physician-Scientist grant for physicians
 - New York student grant for a New Yorker
 - etc

The basic principles of grantsmanship apply:

- The potential funding organization/mechanism should “match” the investigator, the **study** and the environment.
 - Basic science grant for basic science
 - Epidemiology grant for epidemiology
 - Clinical sciences grant for a clinical study
 - Pulmonary diseases grant for an asthma study
 - etc.

The basic principles of grantsmanship apply:

- The potential funding organization/mechanism should “match” the investigator, the study and the **environment**.
 - Non-profit grant to hospitals, universities, etc
 - Small business grant to a small business
 - Dept of Pathology grant to Pathology investigator
 - etc.

Let's find a funding organization!

- Ask your mentor for advice and suggestions.
 - You're not the first person to start a career looking for funding!
 - Your mentor will likely know what approach has been successful (and what has not).
- We'll work on line with examples from the audience.
- <http://research.bwh.harvard.edu>

The basic principles of grantsmanship apply:

- Take advantage of the BWH environment!
 - Shared resources
 - Core facilities
 - <http://www.rics.bwh.harvard.edu>
 - <http://bwhbriresearchintranet.partners.org/>
 - <https://v2.ramscompany.com/>
- We'll look at some of these on-line.

The basic principles of grantsmanship apply:

- Your writing should be simple and clear.
- Illustrations should be simple and easy to read.
- You **MUST** follow all formatting guidelines.
- You **MUST** follow all application rules.

Letters of support are key for first grants

- Investigator Qualifications
- Institutional Commitment
- Resources
- Your Career Plan
- **Make it easy for your letter-writers, as their letters will address these issues! Your written request for a letter should contain the following:**
 - A cover letter requesting their letter of support.
 - An up to date c.v.
 - A copy of your best paper or two, even if they're an author, too!
 - A statement of your plans for the future (can be in the cover letter).
 - Instructions from the granting agency regarding what they're to do with their letter. Include a stamped, addressed envelope if possible.

} REMEMBER THESE?

Don't make it easy for the reviewers!!

- There are almost always more good applications submitted than there is funding available to support them.
- Grant review committees look for simple reasons not to fund grants, because the task of reviewing is difficult.
- **Be sure you've followed all the rules!!!**

Before submission

- Most grants are awarded to your institution, not to you personally.
- You **MUST** have administrative authorizations
 - Divisional and Departmental approval
 - Human studies approval
 - Animal Care and Use Committee approval
 - Hazardous materials approval
 - Radiation safety approval

The basic principles of grantsmanship apply:

- Complete a late draft early!
- Get help early!
 - Channing Lab Editorial Service
 - 617-525-2546 617-525-2547
 - <http://www.niaid.nih.gov/ncn/grants/default.htm>
- Get your grant reviewed early!
 - Ask your mentor or other experienced grant-writers to review your grant critically, well before the submission deadline.

The basic principles of grantsmanship apply:

- Rules for administrative review of your grant application vary by Division and Department at BWH. This is true at other institutions too.
- Some Divisions REQUIRE the grant be submitted internally up to a month before the actual deadline.
- DON'T be surprised by these rules!

Make your work count!

- Consider dual submission to increase the likelihood of success
 - It is perfectly acceptable to submit ***EXACTLY*** the same grant to two (or more) different organizations, with appropriate format changes.
 - **You may only keep one of the awards.**

Parting thoughts

- Writing grants is always an educational experience. It's a learned skill.
- Writing grants can be a humbling experience.
- Writing grants is often an iterative experience.
- **DON'T GIVE UP!**

K Awards

Choosing

Matthew Layne, PhD

&

Applying

Rebecca Baron, MD

Pulmonary Division, Dept of Medicine

Overview

CHOOSING

- Which K is right for you?
- Eligibility issues

APPLYING

- When to apply?
- Where to send it?
- What goes into a K grant
 - Focus on Non-scientific issues

Where to Get Accurate Information?

NIH—(type K Kiosk in Google, easy to find)

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

K Kiosk - Information about NIH Career Dev Awards

Career Award Wizard- Helps you select the right career award

Visual Guide to NIH Career Development Awards

- Research doctorate = PhD
- Health Professional doctorate = MD

Career Award Data and Administrative Information

- Funded Career Awards
- Career Award Success rates

Goals and Purpose of K Awards

- Ensure that diverse pools of highly trained scientists are available in adequate numbers and in appropriate research areas to address the Nation's biomedical, behavioral, and clinical research needs
- Provide support and protected time (3-5 yrs) for an intensive, supervised career development experience in the biomedical, behavioral, or clinical sciences leading to research independence

Big Picture Rules/Eligibility

- Candidates must be MD or PHD U.S. citizens, non-citizen nationals, or permanent resident and commit a minimum of 75% of full-time professional effort conducting research and relevant career development activities specified in the application. K99/R01 VISA long enough for project.
- Must demonstrate and justify the need for a 3-5-year period of additional supervised research experience.
- Planning, direction, and execution of the proposed career development program and research project will be the responsibility of the candidate and his/her mentor.

Big Picture Rules/Eligibility

- The proposed career development experience must be in a research area new to the applicant and/or one in which an additional supervised research experience will substantially augment the research capabilities of the applicant.
- The candidate should provide a plan and proposed timeline for achieving independent research support by the end of the award period. New R01 rules!
- May not concurrently apply for or have an award pending for another NIH career development award. Up to two revisions of an application will be accepted.

K Grants —Numbers and Names

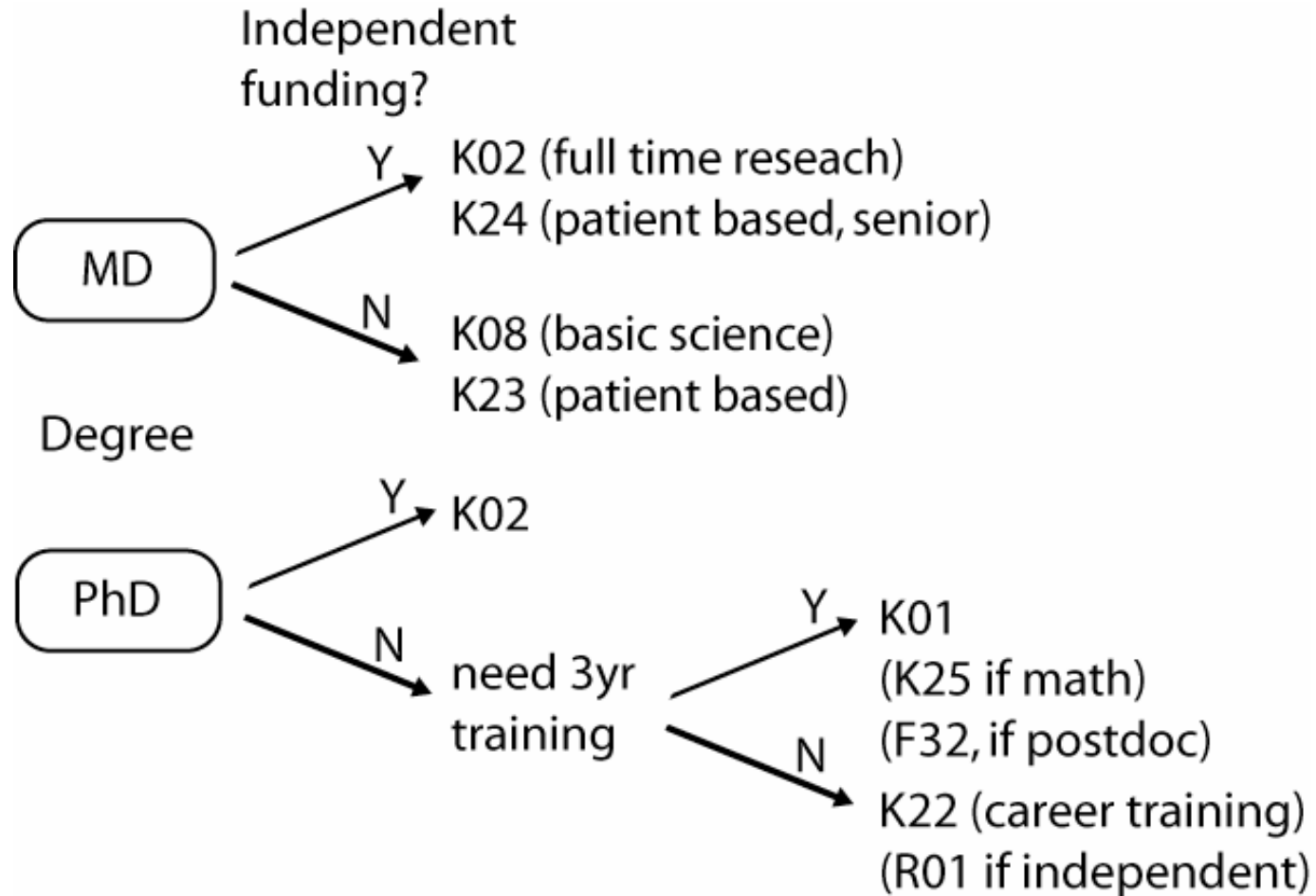
- K01** **Mentored Research Scientist Development Award**
- K02** **Independent Scientist Award**
- K05 Senior Scientist Award
- K07 Academic Career Award
- K08** **Mentored Clinical Scientist Developmental Award**
- K12 Mentored Clinical Scientist Developmental Program
- K18 Career Enhancement Award for Stem Cell Research
- K22 Career Transition Award (intramural at first)
- K23** **Mentored Patient-Oriented Res Career Dev Award**
- K24 Mentored Quantitative Research Career Award
- K26 Midcareer Investigator Award in Mouse Pathobiology
- K30 Clinical Research Curriculum Award
- K99** **Pathway to Independence Award**

K Awards at BWH

	<u>2004</u>	<u>2006</u>	
K01	12	11	
K07	2	5	
K08	52	53	clinician
K12	1	12	clinician
K22	1	0	
K23	15	14	clinician
K24	5	5	

= \$11.8 million

Career Award Wizard



NIH Pathway to Independence Award K99/R00

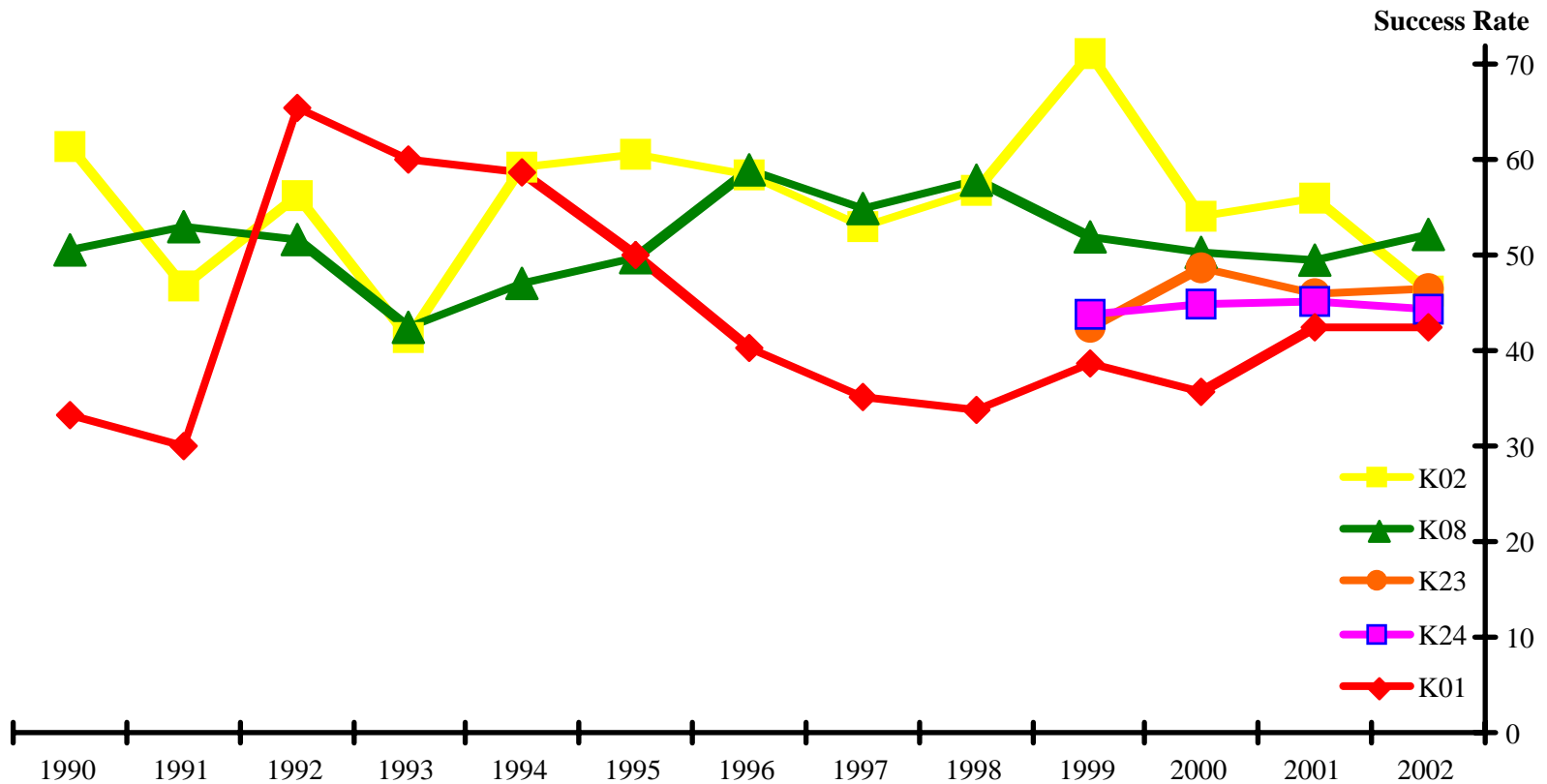
Opportunity for promising postdoctoral scientists to receive both mentored and independent research support from the same award.

Initial phase will provide 1-2 years of mentored support (\$90,000)

Followed by up to 3 years of independent support contingent on securing an independent research position (\$249,000).

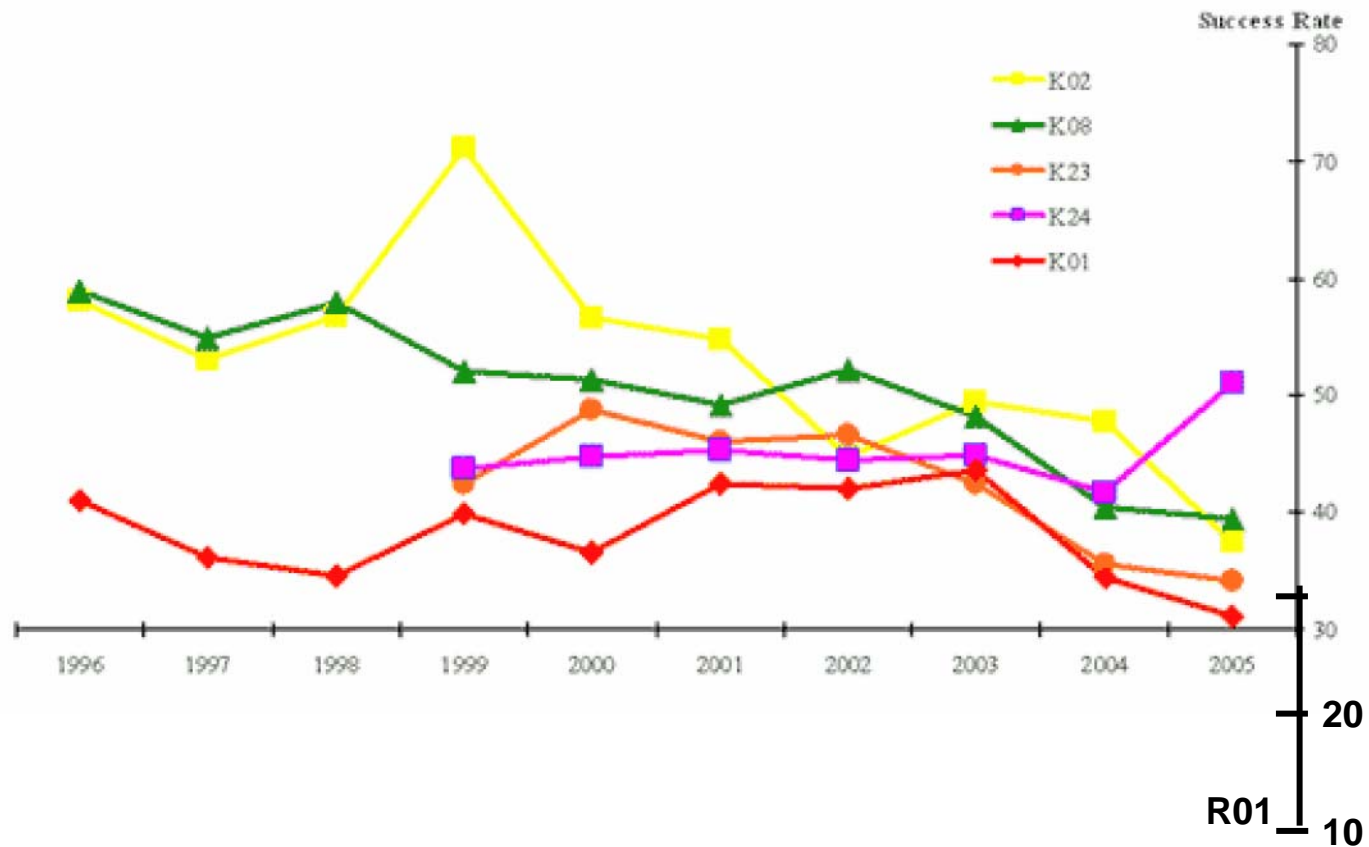
Award recipients will be expected to compete successfully for independent R01 support from the NIH during the career transition award period.

Overall Your Chances Are Good Were Good?



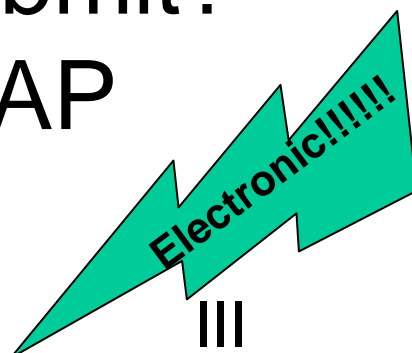
Overall Your Chances Are Good Were Good?

NIH Success Rates for Selected *K* Activities
Fiscal Years 1996 - 2005



When to Submit?

Early/ASAP



Cycle	I	II	III
Receipt 2007	Feb12	Jun12	Oct12
Review Dates	June	Oct	Feb
Start Date	Dec	April	July
Plan on Revising	Mar	July	Nov
Start Date	Dec	April08	July08

Time first submission to funding = 10 months
 With 1 revision (miss 1 cycle) = 17 months!

Wrap Up—CHOOSING!

1. Talk to your Mentor about your career plans [EARLY]
2. Talk to your Division Chief/Dept Chair [EARLY]
--> To be competitive, promotion to Instructor
3. Talk to your Division Grants Administrator [EARLY]
4. Get an NIH eCommons account (get ready for electronic)
5. Get Examples of Successful K awards!
6. Determine which Institute to send your grant
7. Consider contacting the Program Official at NIH to verify eligibility[EARLY]

APPLYING!

3 Equal Parts to K Awards (This applies to most K01, K08, K23)

1. Candidate—This is you
2. Career Development Plan
 - Environment-Institutional Commitment
 - Resources
 - Mentor
3. Research Plan

Prepare the K Application

Start at least 4-6 months before deadline

GET READY FOR ONLINE

Instructions, Instructions, Instructions

- a. Current Forms
- b. Administrative details
- c. Font, length of application
- d. Animal/Human protocols, Resources
- e. Mentor, 3 Letters of Recommendation
- f. Institutional commitment—do you have an advocate here to help with your career?
- g. Scientific plan, organize your data--AIMS

Candidate: 3 Pages

- A. Background (About 1 page)
 - How your background brings you to superb candidacy for this training opportunity.

- B. Career Goals and Objectives (About 1/2 page)
 - e.g., academic clinician-scientist taking care of ICU patients (no more than 15% time) with ultimate goal of becoming an independent investigator studying neutrophil biology

- C. Career Development/Training Activities
 - Earlier in application: Advisory Committee

Candidate: 3 Pages, Cont'd

C. Career Development (1.5 Pages)

-Setup: Phase 1, Coursework (Years 1-2) then
Intensive Research Phase (Years 3-5)

1. Coursework, Seminars, Meetings (% effort)
 - a. Formal courses (list) at HMS
 - b. Responsible conduct of research
 - c. Seminars (list), lab and national meetings
2. New Techniques (list)
3. Clinical Activities (no more than 15%)

Mentor

What to look for in a K mentor (maybe this is too late?)

1. Identify a mentor with extensive appropriate research experience for the project and development plan. Co-mentors are sometimes appropriate.
2. Track record of former trainees and what are they doing now?
3. Recognized in the field
4. Sufficient financial resources

Mentor's Statement (3-5 Pages)

You may need to help with this (ie, write it)

1. Their qualifications and experiences as research supervisor--list of past trainees.
2. Mentoring plan and supervision--coursework.
3. Plan for transitioning to independence and how the research training plan will allow you to do this in the context of the work ongoing within the lab.
4. Agree to provide annual evaluations in progress report.

Environment/Institutional Commitment

- The applicant institution must have a well-established record of research career development activities and qualified research faculty to serve as mentors.
- The institution must demonstrate a commitment to the development of the candidate as a productive, independent investigator and be willing to allow the protected time needed by the applicant.
- The candidate, mentor, and institution must describe a career development program that maximizes the use of relevant research and educational resources, and propose qualified faculty as mentors in the specific research area

Dept Chair Letter—(ex. Dr Loscalzo fill in form)

I am pleased to provide this letter of institutional support for Dr. xxxxxx, who is applying for a Mentored Clinical Scientist Training Award. Dr. xxxxx is an exceptionally talented physician-scientist who has already distinguished himself/herself in research and has the potential for a brilliant academic career. He/She will work with Dr. xxxxxx to develop xxxxxx.

Institutional Environment—The Brigham and Women's Hospital (BWH) is located in a fertile research environment at Harvard Medical School. In addition to a full range of internationally recognized clinical investigators at BWH who are expert in a broad spectrum of human disease pathobiology, local sister institutions including the Harvard Medical School Quadrangle, the Dana-Farber Cancer Institute, the Beth-Israel Deaconess Medical Center, and the Children's Hospital Medical Center, complement and enhance these strengths. The centers house a rich collection of investigators in all areas of hematology, hematologic malignancies, and cancer biology, including cell cycle analysis, cancer genetics, tumor suppressor genes, immunology, angiogenesis, transcription, hematopoiesis and tumor biology. Intellectual interactions among physician scientists are fostered by weekly research seminars in which principal investigators as well as postdoctoral fellows present their most recent work. Other weekly seminars include: 1) BWH Division of Hematology seminars in topics related to normal and malignant hematopoiesis, coagulation, thrombosis and hemoglobinopathies; 2) Dana-Farber Cancer Center seminar series on molecular and cellular topics in oncology, which include speakers with international reputations; and 3) Harvard Medical School and University seminars. The Harvard Medical area is particularly rich in opportunities for intellectual exchange and collaborations among investigators from diverse fields.

Institutional Commitment to the Candidate's Development

Dr. xxxx's time in the laboratory will be protected so that he/she can develop into an independent investigator. His/Her clinical commitment will be limited to one morning of clinic per week throughout the duration of this award, and there will be no inpatient, on-service responsibilities during this award. Dr. xxxx's remarkable progress in the relatively short time that he/she has been in the xxxxxx laboratory is based, in part, on a strong track record in laboratory investigation during his/her career development, and provides a high level of assurance that he/she will be successful in his/her pursuit of a career as an academic physician scientist. We enthusiastically support him/her in this effort.

There is further assurance of Dr. xxxxxx successful career transition to an independent investigator through mentorship with **Dr. xxxxxx, who has a longstanding track record of success with his/her trainees**. Dr. xxxxxx is currently xxxxxxxxxx, and is, thus, well qualified to serve as a mentor. Perhaps most importantly, as documented in his mentor's letter, Dr. xxxxxx has mentored more than xxxxx physician scientists like Dr. xxxxxx, who were xxxxxx, and who now hold junior faculty positions at xxxxxxxxxx.

Although trainees from the xxxxxx laboratory are often recruited to other institutions and have outstanding opportunities for career development at other centers, we are hopeful that Dr. xxxx will be among those trainees who will choose to pursue his/her academic career in our department. **To this end, we have identified laboratory space for him/her and will continue to provide him/her with protected research time and appropriate salary and other laboratory support.** Owing to Dr. xxxxxx track record of success, his/her commitment to xxxxxxxxxx research, and the very fine research environment in which he/she will work, I have every confidence that he/she will become an outstanding physician scientist.

There is often concern that a large Department like ours does not have sufficient commitment and personal interest in the relatively junior recipients of K awards. I wish to assure you that this is not the case. Trainees like Dr. xxxxx are our future faculty and the future of our department, and we are **very interested in providing them with the resources they need to succeed and sufficient space and resources to retain them as junior faculty.** At any point in time, there are at least a dozen recipients of K awards within the Brigham and Women's Hospital Department of Medicine. Many of them remain on our faculty, and those who do not often choose positions at equally fine institutions. Dr. xxxx has secured a position as Instructor, which is the entry-level position for most clinical department faculty at Harvard Medical School. As soon as he/she has met relevant institutional criteria, he/she can be advanced to Assistant Professor. **His/her career path and a commitment to provide him/her training, salary, and advancement are not dependent on his/her receipt of the K award.** Receipt of the award would, of course, be a great honor and would help him/her in his goal to become an independent investigator.

We view Dr. xxxx as one of our brightest trainees and have very high expectations for his/her success in the coming years. There is no doubt that this career development award will allow him/her to develop into an outstanding independent investigator. Thank you very much for your consideration of this superb applicant.

Sincerely yours,

Joseph Loscalzo, M.D., Ph.D

The Unofficial Wrap-Up

- #1: Apply...there's really no downside.
- #2: Apply as early as is feasible: there's really no upside to not being funded.
- #3: Start thinking, talking, and strategizing about applying early: mentor, letter-writers, division chief...allow a minimum of 8 weeks for full-time writing.
- #4: Steal as many grants from as many people as you can (both funded and unfunded).
- #5: Write AIMS and have lots of people read them...it takes a village.

More Unofficial Wrap-Up

- #6: DON'T leave the personal statement till last...an educational plan is critical.
- #7: “Supervise” your mentor and institutional letters.
- #8: Have as many people read your grant as possible...it really takes a village.
- #9: Everything always takes longer than you think.

The Final Wrap-Up

#10 through #20:

DON'T GET DISCOURAGED

It's worth the pain.

What makes a good grant application great?

Karl Münger, Ph.D

What makes a good grant application great?

There are no universally applicable rules!

R01 versus R21

As a general rule, your first grant should be an R01 not an R21

R21 gives only two years of support

For a new investigator

R21 does not offer ANY advantages over R01

Who is a “new investigator”

Has never been a PI on a PHS-supported research project other than

a small grant (R03),

Academic Research Enhancement Award(R15),

exploratory/developmental grant (R21),

or K series career awards except K02 and K04.

“New Investigator Bonus”

Less preliminary data

Summary statement will be available more quickly

Get funded with percentile rankings that are un-fundable for established investigators

But your grant is still reviewed by a standard study section

How are grant applications reviewed?

Every application is assigned to an initial review group
(IRG-"Study Section")

Is it the right study section?

Check the study section rosters

Talk to colleagues who work in the same field

Write a cover letter, requesting review by specific IRG

Call your program person

How are grant applications reviewed?

Each application is reviewed by 3 reviewers (at least)

Each reviewer gets 6-10 grants to review
(It takes at least half day to review each grant!)

Each reviewer ranks the grants:
Top half/bottom half

You do not want to make it into the lower half

Your proposal needs to stand out to a reviewer who does not know you and may not be intimately familiar with what you propose

How are grant applications reviewed?

SRA (Scientific review administrator) will compile a list of such grants

Every reviewer gets 6-10 grants to review

The primary and secondary reviewers each write in depth criticisms

Each reviewer ranks the grants:
Top half/bottom half

Prior to the meeting each reviewer submits their list of grants that are in their respective bottom half

Generic Structure of Research Plan

Background and Significance

Succinct review of relevant literature

Conceptual Framework

“xx is not known – it is important to know this because it will address a critical question in the field and has general implications as well”

“We have a good model system and appropriate reagents are available or could be developed based on the expertise in the lab”

“Specific aims address the following specific aspects of the overall question”

Set up the problem, how will the proposed research fill critical gaps of knowledge in our understanding of the biological process(es) involved

Specific Aims

Generally 2 to 3 specific areas that you will plan address

Spell out as:

Aim 1: To determine the mechanism of xx during yy using zz

or

Aim 1: Does xx regulate yy during zz?

Under each heading write one or two sentences summarizing the main goal of the particular aim and how it pertains to the overall theme of the proposal, clearly state **hypotheses** that drive each aim

Take the meaning of the word “specific” literally!

Do not propose broad “descriptive” analyses

Preliminary Results

Preliminary data have to support feasibility of each aim

Present published work succinctly, add paper to appendix

Show unpublished data in more detail, particularly work that you have accomplished in your own laboratory

You will not automatically get the benefit of doubt to achieve something just because you did it as a postdoc

Convince the reviewer that your laboratory can achieve what you propose

Experimental Design and Methods

Start with a brief rationale and summary of preliminary data for each specific aim

State hypothesis to be tested

Conceptual description of the techniques involved (no buffer lists)

Positive and negative controls

If a novel technique is to be developed name collaborators who have experience with the technology

NEW INVESTIGATORS ARE NOT GIVEN THE BENEFIT OF DOUBT THAT THEY CAN DO IT

Experimental Design and Methods

How will the data be analyzed and interpreted?

Discussion of the different outcomes:

How will they be interpreted?

How does it affect the next aim?

Alternative approaches - what if a given technique does not work?

Provide a short Summary of the Aim

Convince the reviewer that you can achieve what you propose

Aims should not be just *descriptive* but **mechanistic**

Later aims cannot depend on specific outcomes of previous aims
No “sudden death aims”

Propose aims that test (never “prove”) a hypothesis, and where every outcome is interesting, no yes/no aims.

Propose a set of logical aims that will address the question that you address (“reduction to practice”)

Concluding Remarks/Perspectives

optional

Summarize the motivation for your research plan

Summarize the most important follow-up questions that can be addressed once the experiments you propose have been performed.

Your last chance to convince reviewers that what you propose is really cool and should be funded

... and all of this has to fit on 25 pages!

Make the reviewer **want** to read your proposal

Make the reviewer **remember** your proposal
after reading all of them

Reviewers are experts they but may not be intimately familiar with
your field of research

You want them to understand what you propose and why,
after reading your proposal once!

Make it easy for them
Do not make them guess

Individual sections should be somewhat redundant; reviewers may not read them all in detail or necessarily in the order that they are listed

Be realistic; do not propose un-unrealistic amount of work

Crisp, clean, clear writing - - NO TYPOS!!

Simple model figures that lay out the basic concept and how individual aims address specific hypotheses

Read other proposals, have others read your proposal

cite the work of others in the field

Start early

DO NOT SUBMIT ANYTHING THAT YOU ARE NOT COMPLETELY
HAPPY WITH!!

ANYTHING LESS THAN A 100% EFFORT HAS NO CHANCE

Budget

Approved budgets for junior investigators are in the \$200,000 to \$225,000 (depending on animal use)

Your effort on your first grant should be between 25 and 40%

Plan your research plan accordingly

Remember that your personnel is not as experienced as you are

OK?

You gave it your “best shot”

-

You did not get it

- a) your application scored in the lower half (“unscored”)
- b) You got a score but the percentile is not fundable

Read the Summary Statement

Put it away for a few days - it's not personal

Read it again

Have someone else read it too, preferably someone who has served on a study section

Try to figure out what's really wrong with your proposal

Do the reviewers agree on key points?

If your proposal received a score, read the "Summary of the Discussion"

Call your program person

DO NOT CALL THEM BEFORE YOU CALMED DOWN

Is there a more appropriate study section for the proposal?

Why did the reviewers not get excited?

Is the writing clear?

Do I cite all the work in the field (even the part that you do not like)?

Do I enlist collaborators for specific technologies?

Is each of the aims fully developed?

Do I consider alternative strategies?

Is the research plan overly ambitious?

Is my proposal focused on a single theme?

Do I have sufficient preliminary data?

Is the proposal exciting, cool?

Is it mechanistic or just data collection (fishing expedition)?

Decide on a strategy for re-submission

Does the proposal require major surgery?

Why did the reviewers not get excited?

Do I need additional preliminary data?

Can I publish a manuscript on this?

Do I need new collaborators?

A letter from my former PI stating that (s)he will not compete with you on this?

Don't just throw it back doing cosmetic changes

Write a compelling introduction to revisions

Thank the reviewers for their comments, remember they each spent at least half a day working on it (if it was not scored)

Address each of the major points of each reviewer and explain the changes; do not be combative

Clearly point out progress/new preliminary data

Highlight if you changed the focus or if you dropped certain aims and replaced them

Have someone help you with this!

You got funded!

Be happy for a few days, crack open the Champagne bottles!

Then, be afraid, be very afraid

Start thinking how to competitively renew your grant in 3 to 4 years!

DO NOT IMMEDIATELY WRITE ANOTHER GRANT PROPOSAL

Make progress on your grant

Communicate regularly with your program official at NIH

Go on a study section, see how things work!

Take annual noncompetitive renewals EXTREMELY serious

Am I on track?

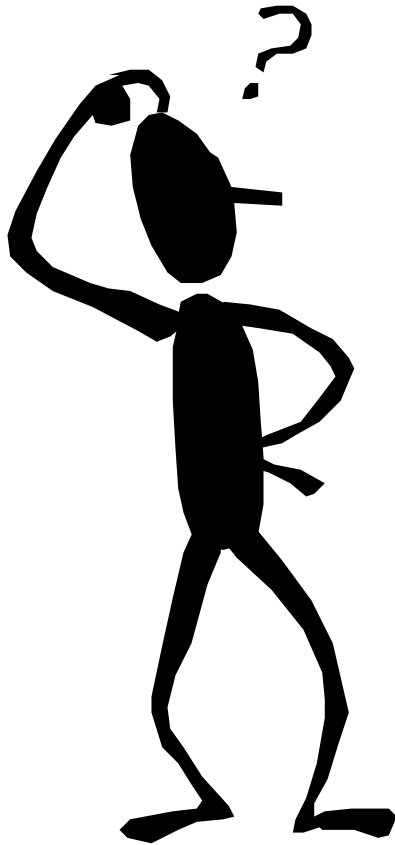
Do I publish papers? (1-2 a year)

Try to get additional money for the lab from non-federal sources, use these develop new areas of research in the lab

Submit a new NIH grant based on this work in year 2 or 3

Remember your NEW INVESTIGATOR BONUS will be gone when you competitively renew or when you submit your second NIH proposal!

What happens to my application at the NIH?



The Study Section

Administrator: make assignments,
(SRA) enforce NIH policies,
“write up” summary statements

Chairperson: work with the SRA in preparation
chair the study section meeting

Regular members: review applications
vote on all applications

Temporary (*Ad Hoc*) members:
same rights as regular members

The criteria

- Significance
- Approach
- Innovation
- Investigator
- Environment

Overall evaluation

Significance:

Previous: (-2004)

Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

New: (2005-)

Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge **or *clinical practice*** be advanced? What will be the effect of these studies on the concepts, methods, ***technologies, treatments, services, or preventative interventions*** that drive this field?

Approach:

Previous: (-2004)

Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

New: (2005-)

Are the conceptual ***or clinical*** framework, design, methods, and analyses adequately developed, well integrated, ***well reasoned***, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

Innovation:

Previous: (-2004)

Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

New (2005-):

Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, **tools**, or technologies for this area?

Investigator:

Previous (-2004):

Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

New (2005-):

Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? ***Does the investigative team bring complementary and integrated expertise to the project (if applicable)?***

Environment:

Previous (-2004):

Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

New (2005-):

Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed ***studies benefit from*** unique features of the scientific environment, ***or subject populations***, or employ useful collaborative arrangements? Is there evidence of institutional support?

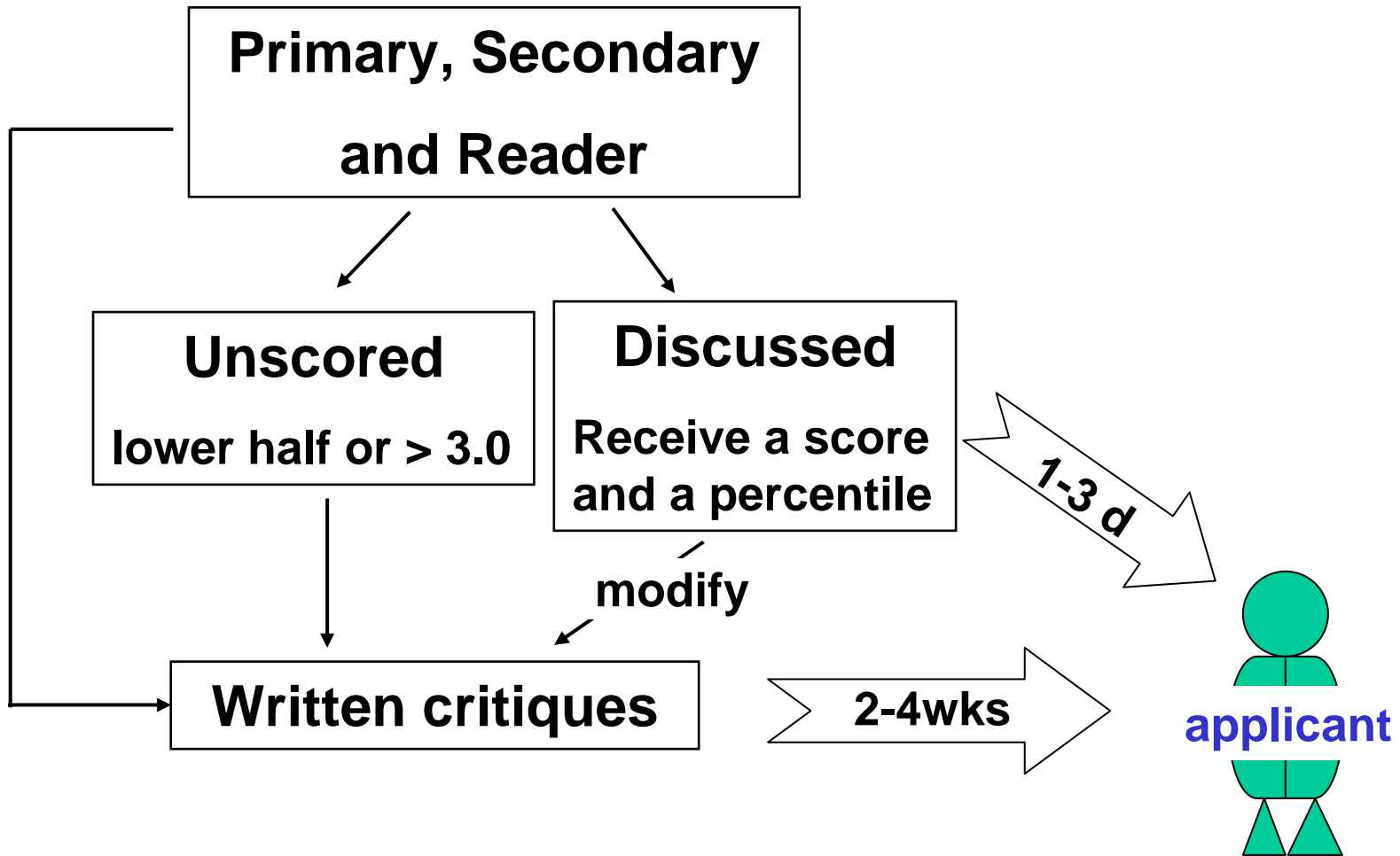
OVERALL EVALUATION:

In one paragraph, briefly summarize the most important points of the Critique, addressing the strengths and weaknesses of the application in terms of the five review criteria. Recommend a score reflecting the overall impact of the project on the field, weighting the review criteria, as you feel appropriate for each application. An application does not need to be strong in all categories to be judged likely to have a major scientific impact and, thus, deserve a high merit rating. For example, an investigator may propose to carry out important work that by its nature is not innovative, but is essential to move a field forward, **or improve clinical decisions or outcomes.**

Scoring system

- 1.0-1.5 outstanding
 - 1.5-2.0 excellent
 - 2.0-2.5 very good
 - 2.5-3.5 good
 - 3.5-5.0 acceptable
-
- Percentile rank
 - Unscored

Typical Treatment of an Application



The Discussion

The process:

The internet-assisted review (IAR) facilitate the discussion at the meeting.

The issues:

Scientific: hypothesis-driven vs. discovery, innovative, solid/honest/thoughtful

Nonscientific: independence, human subjects, animal welfare

What makes a proposal fly?

Good science

Responsive

Ammunition for the reviewers

Interactions with NIH

Before the review

- Assignment
- Supplemental
- Corrections

After the review

- Contact NIH staff
- Do NOT contact study section members

What's new about the NIH grant review?

CSR has completed the reorganization of its review groups.

Web-based submission is under the way and is likely followed by web-based review.

A shorter research proposal is being considered, please send in your thoughts.

New investigator credit.

Learn more at:

<http://cms.csr.nih.gov/>

RESPONDING TO THE "PINK SHEET"

Julie E. Buring, ScD

December 8, 2006

Review Process

- An application is assigned to a primary and secondary reviewer, plus possibly a discussant or reader.
- These individuals only provide detailed comments; other study section members may skim grant, usually at most read abstract, add oral comments.
- When the reviews are posted electronically, the reviewers are asked for their initial scores.

Review Process

- Two ways a grant may be not funded
 - **Triaged, or unscored (UN)**
 - primary and secondary reviewers scored in lower half of applications (50-60%) and no exception was requested at meeting
 - grant not discussed, critiques sent as is
 - **Scored (range 1.0-5.0), but not in fundable range**
 - discussed by group
 - score reflects group consensus
 - reviewers' comments modified to reflect discussion

Summary Statement

- Once applications are reviewed, the results are documented by the SRA in a summary statement and forwarded to the PI and the Institute where the funding decision is made.
- First you get just a **score and percentile** (calculated using the current and previous two rounds as a base), or a **notation of “UN”** (electronically). Subsequently you get the **pink sheet** (electronically).

Summary Statement

The Summary Statement contains:

- Priority score and percentile rank (will be ****'s if triaged)
- Overall resume and summary of review discussion if not triaged
- Essentially unedited critiques from reviewers and comments from other members of study section
- Assessment of inclusion of human subjects, DSMB, and gender/minority/children
- Budget recommendations
- Administrative notes

Review Process

- Read it, then put it aside
- Get depressed, angry, feel misunderstood and underappreciated, then get over it
- Show it to someone else to evaluate the points, tone
- Outline it carefully
- Unemotionally, figure out what to do
- **Never call the reviewers**, call the SRA for further information

Most Common Reasons for Unfunded Grant

- Lack of **focus, too ambitious** (Aims)
- Lack of preliminary results that indicate **feasibility** (Preliminary Work)
- Lack of appropriate **expertise** (Methods)
- Statistical **power**
- **Budget?**

Resubmitting Your Grant

- Include a 2-3 page **Introduction** to the revised grant application – **This is critical.**
 - thank the reviewers
 - acknowledge their points and/or your lack of clarity
 - attempt to address their issues or respectfully disagree/explain why not
 - give overview of significant changes
 - identify specific changes in grant
- Must try to address all their issues because at least one reviewer (but usually not all) will likely be the same. **Take all negative emotion out of the response.**

Resubmitting Your Grant

- Do you **always resubmit** a grant? No
 - It depends on what the issues are

Resubmitting Your Grant

- **How quickly** do you turn the grant around and resubmit?

It depends on how much you have to do

- Remember you have to maximize the second application.
(i.e., the first resubmission - only allowed maximum two resubmissions)
- If changing to a new grant, retitle and resubmit as such.

Resubmitting Your Grant

- What do you do if **new information** or a new study has just come out, at worst scooping your work?
 - Must deal with it head-on – the reviewers will know about it
 - Might change aims or order of aims
 - Might only underscore the importance of your grant

Resubmitting Your Grant

- What do you do if the critique implies that the **science is not important** - it flunks the "so what" test?
 - You have to do a better sell job
 - Discuss the implications of your findings from a research, clinical, or public health standpoint

Resubmitting Your Grant

- What do you do if you think it was an **inappropriate review**, or erroneous criticisms were made?
 - Respectfully disagree, and fully explain why
 - Appeal process

Appeals . . .

- If an appeal succeeds, then the materials originally submitted are re-reviewed by another Study Section.
- No additional materials may be submitted or considered.
- Advantages:
 - If needed expertise was not present, and the significance was not appreciated, then re-review could change the outcome.
- Disadvantages:
 - No new materials can be considered
 - The investigators lose a round
 - The investigators are unable to address concerns

Resubmitting Your Grant

- What do you do if you believe it was assigned to the **wrong study section**, i.e., it was misaligned with the reviewers' expertise?
 - Request study section in cover submission letter.
 - If not yet been reviewed, request change right away – talk to SRA.
 - If post-review, talk to SRA – consider requesting change for next review.

Requesting Change of Study Section

- **Advantages**
 - More appropriate expertise can lead to major change in perception of significance
- **Disadvantages**
 - New concerns are usually generated
 - Previous concerns may not go away
 - Investigators lose a round readjusting and responding to new concerns
- **Best situation: Continuity of review in appropriate study section**

Resubmitting Your Grant

- What do you do if you **don't understand the message** of the pink sheet, i.e., when the words and the score do not appear consistent?
 - Talk to SRA

“The Three R’s”: Rethink, Revise, and Resubmit

- Discuss the review with program staff.
- Address ALL the concerns in the summary statement. Especially the ones you think should be obvious (apparently not to everyone).
- **BE RESPONSIVE!!** Be polite. Remember the review group has spent considerable time reviewing your application and has provided the most constructive feedback possible.
- If you disagree with something, clearly justify your point of view and then respectfully disagree.
- Don't give up.