

Grants 101 Part IV

Behind the Scenes at a Study Section

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What You Have Learned Thus Far from Tom, Monica, and Sheila

- The importance of grants
- The overall structure of the NIH and Institutes
- Grants mechanisms for you
- Grant administration
- Grant preparation

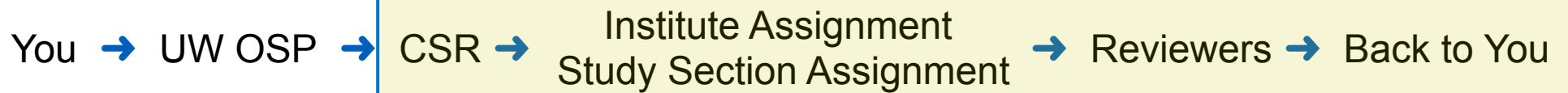
- *Important grantsmanship pointers*
- *Read other's grants – both successful and unsuccessful*

What You Will Learn in This Last Hour

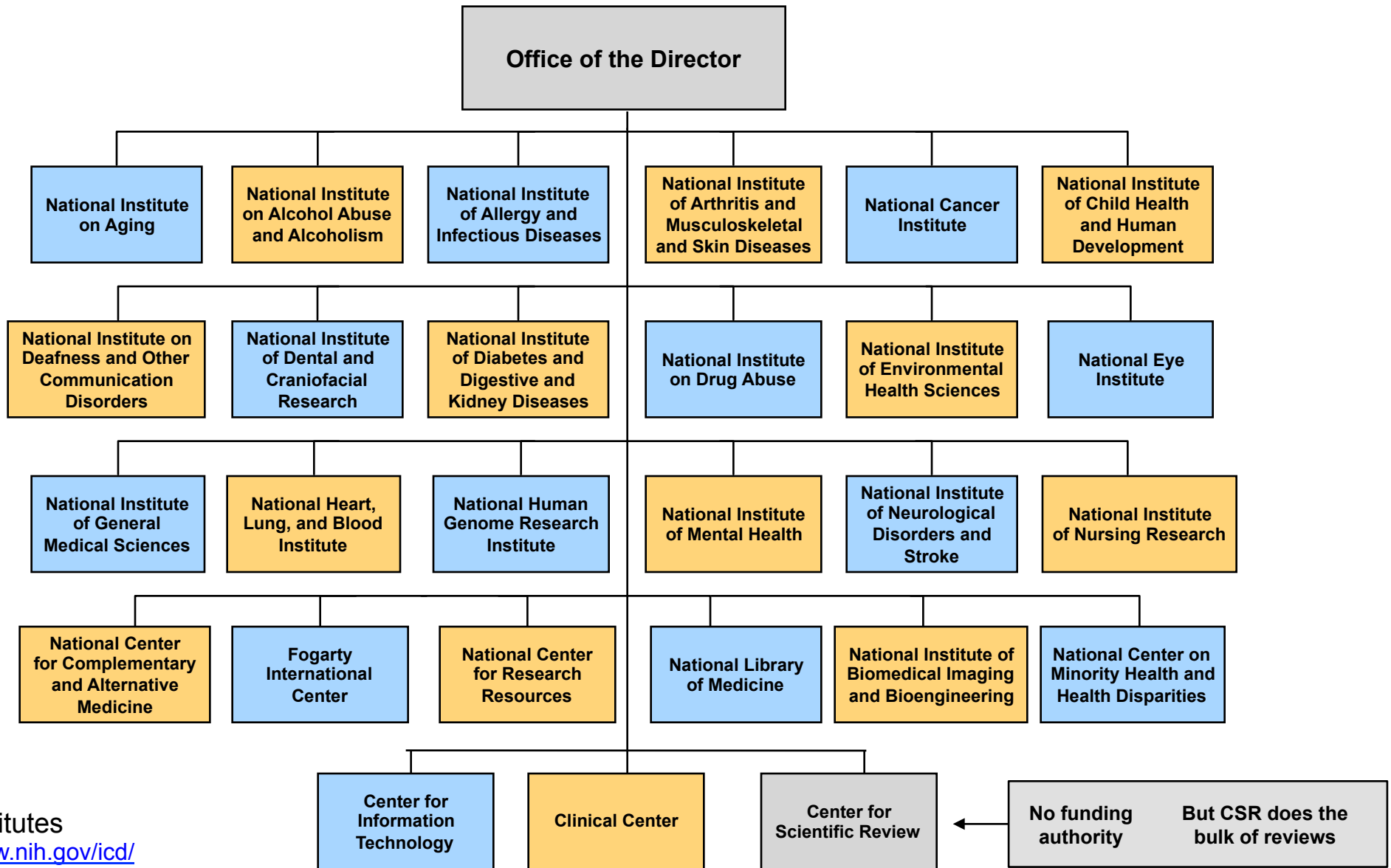
- The grant review process
- Getting into the reviewer's head
- Tips on how to keep reviewers happy and supportive of your proposal

- *Focus on NIH F and K applications – but widely applicable to other mechanisms, including society/foundation grants*

The Fate and Evaluation of Your NIH Proposal

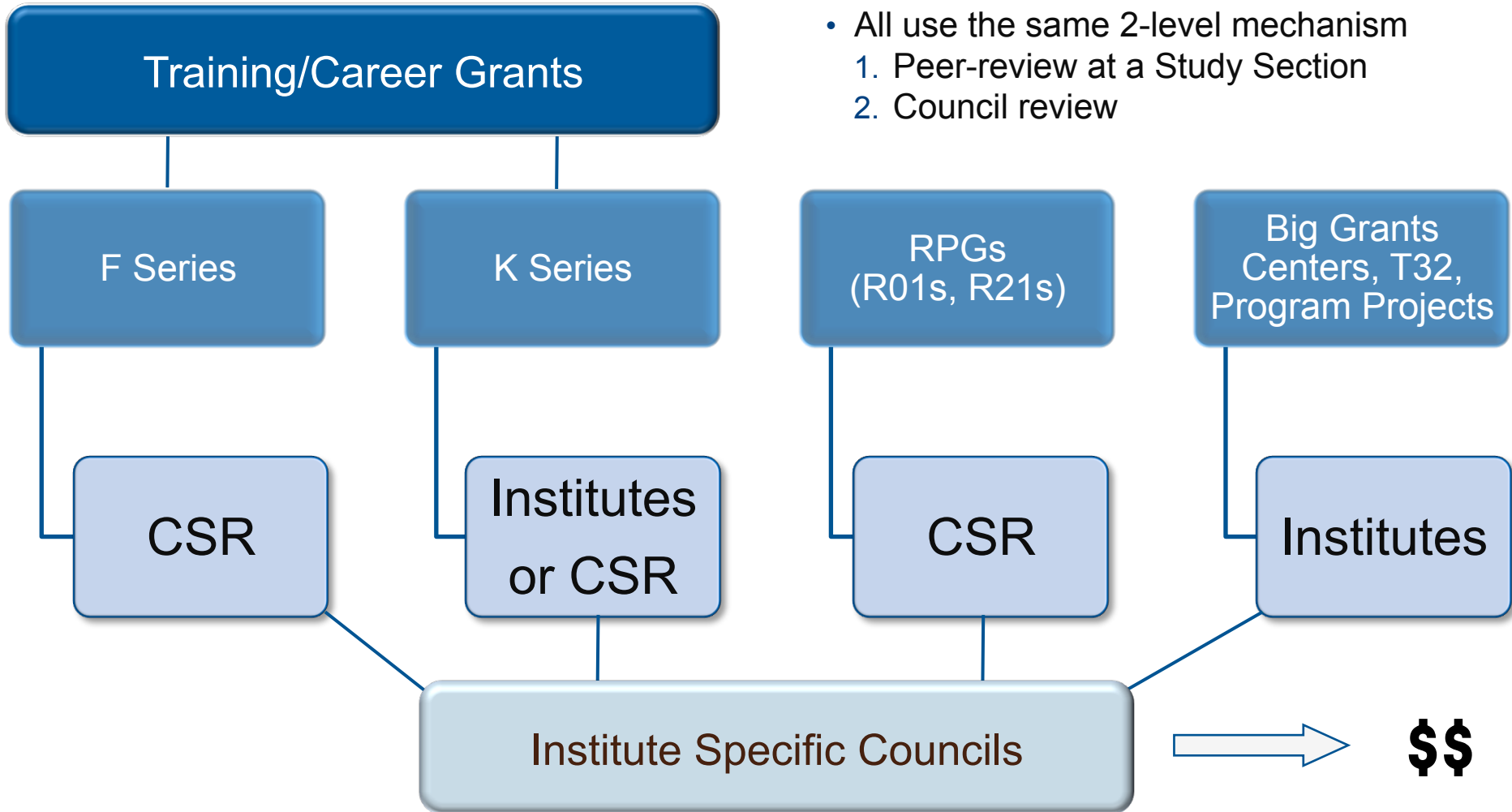


All NIH Institutes Review Grant Applications



Who's Responsible for Review of Application Types?

- All use the same 2-level mechanism
 1. Peer-review at a Study Section
 2. Council review



CSR: Center for Scientific Review

- Receives, assigns, and reviews
- ~80,000/yr (~70% of total)
- 240 SRA (Scientific Review Administrators)
- ~16,000 reviewers per year
- >240 Study Sections
- ~1,600 grant review meetings/yr

Before
Electronic
Submission



Now



The Fate and Evaluation of Your Proposal

You → UW OSP → CSR → Institute Assignment
Study Section Assignment → Reviewers → Back to You

Division of Receipt and Referral

Your can influence this process

Cover Letter:

- Suggest Institute assignment
- Suggest Study Section
- Identify conflicts
- Identify areas of needed expertise
- Special situations
- *Do not recommend specific reviewers*

Pretty dull and needlessly long video of this topic

http://www.youtube.com/watch?v=DuuAGROm_1Q&feature=relmfu

Institute Assignment and Grant Numbers

1 K08 HL102201-01A1
| Activity | Serial # | Suffix
Type Institute Support Year

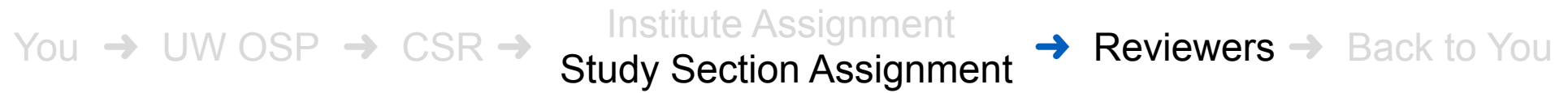
- **Type Code**
 - Indicates whether the application is new, a renewal, noncompeting, or other type
- **Activity Code**
 - Lists the type of grant
- **Institute Code**
 - Two-letter code for the name of the funding NIH Institute or Center
- **Serial Number**
 - Unique 6 digit number that identifies the specific application
- **Support Year**
 - Indicates the current year of support
 - 01 is a new grant
- **Suffix Code (Optional)**
 - Used for supplements, amendments, or fellowship institutional allowances

Institute Assignment and Grant Numbers

K08 HL102201

- All you need for CV, Bios, Other Support

The Fate and Evaluation of Your Proposal



Study Sections



Beginnings of Peer Review of Grants

- **1879:** Response to Yellow Fever
 - \$30,000 bid from the US Army for universities
- **1940:** Need for Penicillin
 - President Roosevelt set up the National Defense Research Committee.
 - Awarded contracts for rapid production projects
 - Identified 700 universities for future contracts
 - 21 penicillin production plants
 - Led to a 97% survival rate for wounded soldiers
- **1942:** Medical Research funding grew from \$2.3 million to \$7.5 million
 - Rating applications with an “A”, “B”, or “C”



1946: The Fundamental Tenets for NIH

1. The only possible source for adequate support of our medical research is the taxing power of the federal government.
2. The federal government and politicians must assure complete freedom for individual scientists in developing and conducting their research work.
3. Reviews should be conducted by outside experts essentially without compensation.
4. Program management and review functions should be separated.

Evolution of Study Sections

1946

The First NIH Study Section



An NIH Study Section Today



Evolution of Study Sections

An NIH Study Section in the Near Future

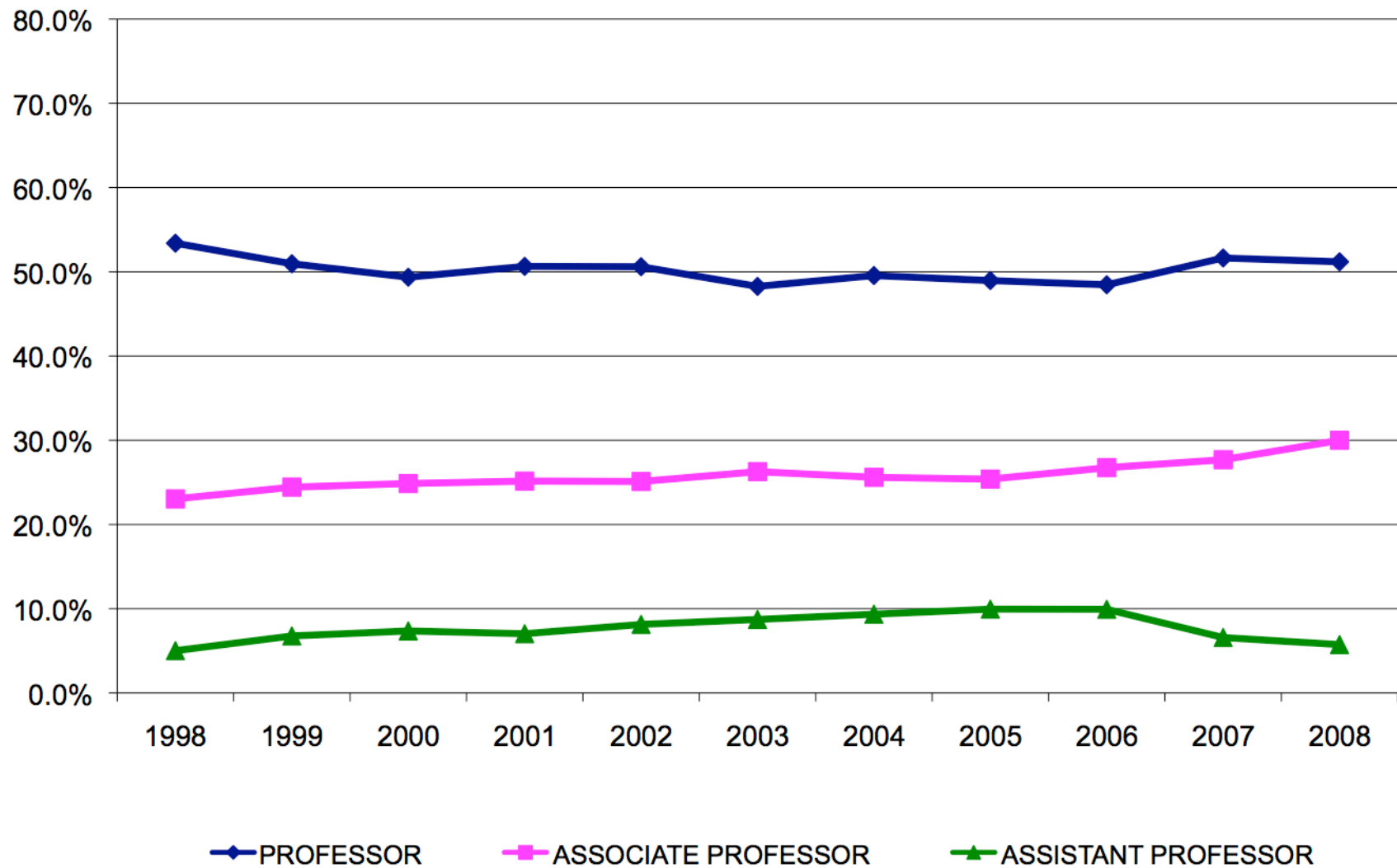
Telepresencing



Study Sections

- Organized into IRGs (Integrative Review Groups)
- Headed by an SRO (Scientific Review Officer)
- 12-25 members, essentially all from academia
 - About ½ are ad hoc reviewers
- 60-100+ applications per meeting
 - ~12 per member
 - 3 reviewers per applications
- Information from CSR web site: <http://cms.csr.nih.gov/>
 - Study section scope
 - Roster of reviewers
 - Policies
 - Schedules
- Study sections are advisory - they do not fund applications.

Most Reviewers are Established Investigators



Who Do You Call?

Program Officer

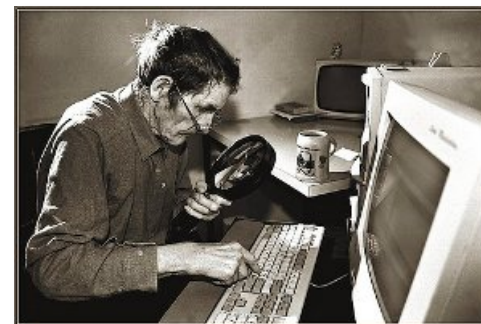
- Institute based
- Before submission
- After initial (study section) review
- Has influence on funding

Scientific Review Officer (SRO)

- CSR based
- During initial review stage
- Has no influence on funding

Review Process - Before the Meeting

- All via the internet
- Applications made available to reviewer 6-8 weeks before the meeting (eCD)
 - 3 reviewers/application
 - 1°, 2°, and 3°
 - Occasion input from others
- Training grants (Fs, Ks)
 - Reviewers typically review applications on a wide range of topics
 - Unlikely to be an expert in all applications assigned



Where and When Do Reviewers Review Grant Applications?

- At home, maybe in bed
- On a plane (likely no internet)
- At the last minute - and thus a bunch in one sitting
- Hence, reviewers can be stressed, anxious, and not terribly sympathetic
- They may lose interest

Don't let the reviewer become...



Baffled,



Bitter,

- *Do not make the reviewer think!*
- *Do not make the reviewer read papers or go to the internet*
- *Do not tick off the reviewers!*



or Bored

F32 Grant Sections

- Face Page
- Table of Contents
- Performance Site
- Project Description (i.e., Abstract)
- Public Health Relevance Statement
- References Cited
- Facilities
- Equipment
- Attachments
- Key Personnel
- Biosketches
- Clinical Trial
- PHS Fellowship Supplemental Form
- Introduction (revised only)
- Specific Aims
- Research Strategy
 - Significance
 - Preliminary Data
 - Approach
- Protection of Human Subjects
- Women & Minorities
- Planned Enrollment Table
- Children
- Vertebrate Animals
- Respective Contributions
- Selection of Sponsor and Institution
- Responsible Conduct of Research
- Applications for Concurrent Support
- Goals for Fellowship Training and Career
- Activities Planned under this Award
- Doctoral Dissertation and other Research Experience
- Sponsor(s)/Co-sponsor(s) Information

F32 Grant Sections That Reviewers Care About

- Face Page
- Table of Contents
- Performance Site
- Project Description (i.e., Abstract)
- Public Health Relevance Statement
- References Cited
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- Applications for Concurrent Support
- Goals for Fellowship Training and Career
- Activities Planned under this Award
- Doctoral Dissertation and other Research Experience
- Sponsor(s)/Co-sponsor(s) Information

K08 Grant Sections

- Face Page
- Table of Contents
- Performance Site
- Other Information
- Project Description
- Public Health Relevance Statement
- References Cited
- Facilities
- Equipment
- Attachments
- Key Personnel
- Biosketches
- Budget
- Budget Justification
- Clinical Trial
- PHS Fellowship Supplemental Form
- Candidate's Background
- Career Goals and Objectives
- Developmental Activities during Award Period
- Training in Responsible Conduct of Research
- Statements by Mentor, Co-mentor
- Institutional Environment
- Institutional Commitment to Career Development
- Introduction (revised only)
- Specific Aims
- Research Strategy
 - Significance
 - Innovation
 - Approach
- Human Subjects
- Women & Minorities
- Planned Enrollment Table
- Children
- Vertebrate Animals
- Select Agents
- Resource Sharing Plan

K08 Grant Sections That Reviewers Care About

- Face Page
- Table of Contents
- Performance Site
- Other Information
- Project Description
- Public Health Relevance Statement
- References Cited
- Facilities
- Equipment
- Attachments
- Key Personnel
- Biosketches
- Budget
- Budget Justification
- Clinical Trial
- PHS Fellowship Supplemental Form
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- Career Goals and Objectives
- Developmental Activities during Award Period
- Training in Responsible Conduct of Research
- Statements by Mentor, Co-mentor
- Institutional Environment
- Institutional Commitment to Career Development
- Introduction (revised only)
- Specific Aims
- Research Strategy
 - Significance
 - Innovation
 - Approach
- Human Subjects
- Women & Minorities
- Planned Enrollment Table
- Children
- Vertebrate Animals
- Select Agents
- Resource Sharing Plan

Scored Review Criteria

Individual Training F-series Grants

- Overall Impact

Review Criteria

- Candidate
- Sponsor, Collaborators, Consultants
- Research Training Plan
- Training Potential
- Institutional Environment & Commitment to Training

Career Development K-series Grants

- Overall Impact

Review Criteria

- Candidate
- Career development plan
Career goals and objectives
Plan to provide mentoring
- Research Plan
- Mentor(s), consultants, collaborators
- Environment & Institutional commitment

Investigator Initiated R-series Grants

- Overall Impact

Review Criteria

- Significance
- Approach
- Innovation
- Investigator
- Environment

Review Process - Before the Meeting

- Scores and critiques are uploaded 1 week before study section
- Each criterion is given a score: 1, 2, 3...9 (best to really bad)
 - These are not discussed at the Study Section
 - But they are included in the Summary Statement you will get
- Each reviewer gives each application an overall Impact Score
 - Impact Score is not the mean of the criteria scores
 - Impact score is key and the only score discussed
- Initial scores and critiques become available to all committee members
- Applications are ranked in order of initial mean Impact Scores
- Lower 40-60% are not discussed (Impact Score of 4.5 – 5.0 and above)
 - Any “triaged” application can be resurrected at the meeting for discussion for any reason
 - Applicants receive the critiques and individual criteria scores
 - Impact Score is not given

Scoring System

- **Criterion Score**
 - Whole numbers: 1-9
 - 1 (exceptional); 9 (um, well let' s just hope you never get a 9)
 - Given by reviewers but not discussed at study section
 - Provided in Summary Statement of all applications (discussed and not discussed)
- **Overall Impact Score**
 - Whole numbers (at first): 1-9
 - Not the mean of the criteria scores
 - Different criteria are weighted by each reviewer
 - Each review recommends a score
 - All committee members score within the range
 - Can vote outside the range, but must state that you are doing so
- **Final Impact Score**
 - Mean of all scores x 10
 - 10 – 90
 - Percentiled against similar applications across 3 meetings (not so for F's and K's)
 - Unknown to the committee (except the chair)
- **Payline**
 - Varies among institutes
 - <http://www.aecom.yu.edu/ogs/NIHInfo/paylines.htm>

Adjectives Used

- 1 Exceptional
- 2 Outstanding
- 3 Excellent
- 4 Very Good
- 5 Good
- 6 Satisfactory
- 7 Fair
- 8 Marginal
- 9 Poor

Criteria Scores

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	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

Impact Score

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

The Review Process - at the Meeting

- Begin at 8 am EST (i.e., 5 am PST)
- Cramped room full of lap tops and several jet-lagged reviewers
- Review Grants in order - best to less best
- 15-20 min per application (shorter is best)
- Go to 6-7 pm
- Bar, eat, bar, sleep
- Repeat next day



The Review Process - at the Meeting

What happens?

- Application is announced and conflicts identified
- Chair asks the 3 reviewers to state their scores
- A moment of silence: all committee members read Specific Aims page (still in a trial phase)
- Primary reviewer discusses strengths and weaknesses using the scored criteria as a guide (but without stating criterion scores)
- Other reviewers concur or discuss differences
- Additional Review Criteria: Animals, Human Subjects, Resubmission
- Discussion opens to the committee
- Reviewers restate their scores (e.g., 2-4-5, 3-3-3)
- A range is established (e.g., 2-5, 3-3)
- Chair asks if anyone plans to vote outside of the range
- Committee posts scores online
- Additional Review Considerations: Budget, Resource Sharing, Bioethics training
- Repeat with the next application in order



Vagaries of Peer Review

- Reviewers are humans; humans err
- Assigned reviewers have the most influence on scoring
- A passionate reviewer (pro or con) can influence the group
- Any committee member can vote outside of the “range”
- Final Impact Score is usually (~85% of the time) close to the initial impact score
 - Scores change >1 point on only 15% of grants
 - Rarely for ESI applications (less than 1%)



Good video of a mock Study Section

<http://www.youtube.com/watch?v=fBDxI6I4dOA>

Review Criteria

Individual Training F-series Grants

- Overall Impact

Review Criteria

- Candidate
- Sponsor & training environment
- Research training proposal/plan
- Training potential

Career Development K-series Grants

- Overall Impact

Review Criteria

- Candidate
- Career development plan
Career goals and objectives
Plan to provide mentoring
- Research Plan
- Mentor(s), consultants, collaborators
- Environment &
Institutional commitment

Review Criteria - Overall

Considering the candidate's (and sponsor's) qualifications and previous research experience, evaluate the proposed training experience as it relates to preparation for an independent research career.

Review Criteria - Candidate

- *“Assess the candidate's potential to become an important contributor to biomedical or behavioral science”*
- Many factors are weighed:
 - Extent and level of education:
 - Undergraduate or graduate degree(s)
 - Fields
 - Academic performance
 - Mentors and institutions
 - Postdoctoral research or clinical experience:
 - Mentors and institutions
 - Fields
 - Productivity (very important)
 - Awards and honors
 - Other relevant research experience and professional training
 - Reference letters
 - Very important
 - Relative ranking: top 1-2%, top 25%
 - Evidence of commitment to a career in research
- Clinical degreed candidates (MD, DVM, DDS, etc.) vs. PhDs

Review Criteria - Your Publications

Tips and Pet Peeves

- One of the most important factors
- An easy and objective way to distinguish among applicants
- Numbers do count
 - So does impact, but...
 - Numbers are objective, impact is not.
- First-author and joint-first-author papers count highest
- What's online must match what's in your biosketch
- Changed your name? Indicate it somehow*
- Complete citations. List all authors.
- Be up-to-date
- Abstracts ≠ Publications

**In 2007, I changed my name from S.J. Germanotta to L. Gaga.*

Review Criteria - Candidate

- Better to change fields or stay put?
 - *“Candidates may choose to remain in a scientific area related to their previous work or shift to an entirely new area of research...*
 - *...[regardless] the proposed training plan must augment the candidate's conceptual and/or experimental skills.”*
 - Should be driven by your interests and career goals
 - Good proposals tend to do well.
- Better to move to another institution or stay put?
 - Moving is always considered to be better than staying in the same environment
 - But some environments (like UW) are BIG
 - Diversity in training and experience is viewed as a big plus

Independence at the Next Stage: R01

- Not a review criterion
- Cannot even be discussed
- However, if you remain associated with your mentor, include a letter from him/her confirming your independence
- Do not include your mentor as paid key personnel

Review Criteria - Sponsor and Training Potential

- *“Assess the qualifications of the sponsor...”*
 - Research expertise
 - Track record as a mentor
 - Reputation and standing
 - Overall productivity and impact of published work
 - Funding
- *“Evaluate the proposed training program...”*
 - Individually tailored to the applicant
 - More than just techniques
 - Didactic and career-enhancing activities
 - Courses, seminars, lab meetings, journal clubs, and scientific conferences
 - Research integrity
 - Opportunities to present and publish - with feedback
 - Opportunities and encouragement to write grants - with feedback
 - Opportunities to interact with other scientists
 - Advisory committee
 - Role of each member
 - Dates and agenda
- *“Evaluate the environment of the host laboratory and the institution as to be conducive to successful postdoctoral training”*



Review Criteria - Sponsor and Training Potential

Common Shortcomings

- Poorly described training plan
- Does not provide opportunities for you to
 - Write grants
 - Write papers
 - Present locally or at meetings
 - Interact with others
- Commitment to training is not apparent
- Poor or no track record with training
- Weak funding
- Lacks expertise in technology being used

These should all be addressed at stage 1

One solution: co-mentor/co-sponsor

Review Criteria - Research Proposal

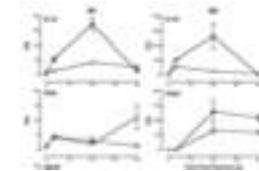
- General approach
- Respective contributions of the applicant and the sponsor
- Must have scientific merit, but emphasis is on training
- *“Check for flaws so severe that they cast doubt on the applicant's or the sponsor's scientific judgment and qualifications or on whether such flawed research can serve as an appropriate vehicle for the candidate's development.”*
- Quite different from an R01



Review Criteria - Research Proposal

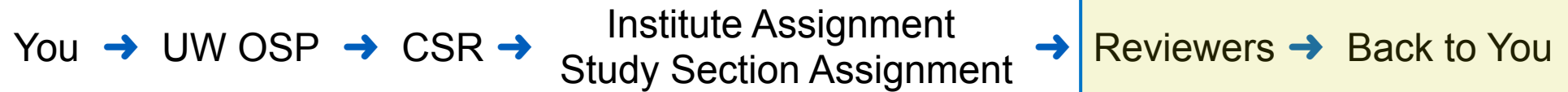
Tips and Pet Peeves

- Hypothesis is incremental, circular, or tautological
- Background is not scholarly or strays from focus
- Not crediting data you did not generate to its rightful source
- No figure numbers, titles, or legends
- Little or pixilated figures are hard to see
- Figures a page or two away from the text
- Aims dependent on preceding aim
- Overly detailed methods
- Overly ambitious
- Not focused
- No discussion on expected findings, interpretation, pitfalls, etc.
- Potential problem limited to mundane technical issues
- No letters from collaborators and consultants
- Worse grammar, typos, following hard the syntax: so *Write Good!!*



Some simple advice: if you cannot see the details in the figures, then neither can the reviewers.

The Fate and Evaluation of Your NIH Proposal



Summary Statement

- Face Page
- Summary of Discussion
- Description (abstract you wrote)
- Overall Impact and Scored Criteria
- Addition Review Criteria
 - Protection of Human Subjects
 - Inclusion of Women, Minorities, and Children
 - Vertebrate Animals
 - Biohazards
 - Resubmission
- Additional Review Considerations
 - Responsible Conduct of Research
 - Budget
 - Foreign Training
 - Resource Sharing Plan
- Additional Comments to the Applicant
 - Excess text in the wrong place
 - Advice for resubmission

Individual Critiques

These do not impact the score

Summary Statement

PROGRAM CONTACT:
Ricardo Cibotti
301-496-0569
cibottirr@mail.nih.gov

SUMMARY STATEMENT
(Privileged Communication)

Release Date: 04/20/2011

Application Number: 1 K08 [REDACTED]

Principal Investigator
[REDACTED]

Applicant Organization: UNIVERSITY OF WASHINGTON

Review Group: AMS

Arthritis and Musculoskeletal and Skin Diseases Special Grants Review
Committee

Meeting Date: 02/28/2011

RFA/PA: PA10-059

Council: MAY 2011

PCC: 4 B

Requested Start: 07/01/2011

Dual IC(s): AI

Project Title: [REDACTED]

SRG Action: Impact/Priority Score: 40 ←

Human Subjects: 10-No human subjects involved

Animal Subjects: 44-Vertebrate animals involved - SRG concerns

Project Year	Direct Costs Requested	Estimated Total Cost
1	114,350	123,498
2	114,350	123,498
3	114,350	123,498
4	114,350	123,498
5	114,350	123,498
TOTAL	571,750	617,490

Summary Statement – Summary of Discussion

RESUME AND SUMMARY OF DISCUSSION: This is a new application for a K08 Mentored Clinical Scientist Development Investigator Award submitted by [REDACTED] from the University of Washington. Dr. [REDACTED] goal is to become an independent physician- scientist studying cutaneous immunology, with a focus on how T cell responses in the skin are regulated. The mentor, Dr. [REDACTED], is a senior investigator with a strong training record and significant experience in mouse immunology, mouse genetic, and specifically the biology of matrix-cell interaction, which is relevant to this proposal. Dr. [REDACTED], co-mentor, has expertise in bioinformatics to provide support for completion of Aim 3. Dr. [REDACTED] is considered a very strong candidate; however, the lack of recent productivity was considered a minor weakness. The career development plan is appropriate but there is no inclusion of bioinformatics training. The environment is outstanding. The committee identified some minor weaknesses. There are concerns regarding the research plan which include the quality of the preliminary data, support for the proposed research plan, interpretation, degree of participation in aim 3, feasibility, and technical issues. The committee also pointed out that the deficiencies in the research plan reflect a lack of adequate mentoring. The committee views the application as very good with some minor weaknesses the career development and research plans.

- Not provided for applications not discussed (duh!)
- Concerns raised here must be addressed in revised application

Individual Critiques

F-series Applications

- Criterion Scores
- Overall Impact

- Candidate
- Sponsor & training environment
- Research training proposal/plan
- Training potential

K-series Applications

- Criterion Scores
- Overall Impact

- Candidate
- Career development plan
Career goals and objectives
Plan to provide mentoring
- Research Plan
- Mentor(s), consultants, collaborators
- Environment & institutional commitment

*Scored
Criteria*

Criterion Scores and Overall Impact

CRITIQUE 1:

Candidate: 3

Career Development Plan/Career Goals /Plan to Provide Mentoring: 3

Research Plan: 4

Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s): 2

Environment and Institutional Commitment to the Candidate: 1

Overall Impact: This is a new K08 Mentored Clinical Scientist Research Career Development Award application from [REDACTED] proposes a five year plan with the goal of obtaining independent investigator status by focusing on investigating the role of CD103 and E-cadherin in maintaining the tolerant state of skin and further investigation of how E-cadherin may regulate Treg gene expression. She has received a strong background in basic immunology (six years total) and has published one first author basic science paper in a high impact journal. She has assembled an excellent team of formal and informal mentors and collaborators and will work in a very good environment with a plan of formal coursework, seminars, meetings and presentations. Minor issues

Summary Statement

SCORED REVIEW CRITERIA

1. Candidate	Please limit text to ¼ page
<p>Strengths</p> <ul style="list-style-type: none">• The scholastic performance of the candidate has improved from many Cs in his undergrad years to straight As in recent years.• The clinical background of this applicant is adequate for this type of project. This provides assurance that the candidate will be directly involved in generating most of the expected data in this large cohort of patients.• The letters of recommendations speak highly of his motivation, excellent thinking skills, and strong commitment and enthusiasm to starting the proposed project. <p>Weaknesses</p> <ul style="list-style-type: none">• The candidate has no prior research experience; however, I do not see this as a significant weakness since he has just finished his residency.• The candidate did not state clearly his career goals. These can only be deduced by reading the three letters of reference.	
2. Sponsor and Training Environment	Please limit text to ¼ page
<p>Strengths</p> <ul style="list-style-type: none">• The sponsor has an outstanding track record in mentoring young scientists.• The laboratory is productive with an average of three publications a year.• The fact that there are 5 post-docs and 2 Assistant Professors will allow the applicant to have daily interactions with knowledgeable scientists.• The applicant will have ample choice to attend pertinent seminars as suggested in the sponsor's training plan. <p>Weaknesses</p> <ul style="list-style-type: none">• It would have been better to perform the exercise tests on patients at the co-sponsor's laboratory which is located in the hospital to save the hassle of daily commuting.• Inclusion of an expert in exercise physiology will strengthen the mentoring team. The sponsors' inexperience in exercise physiology is obvious as the 3-rest periods required with this type of exercise were not proposed.	

Summary Statement

3. [Research Training Proposal/Plan](#)

Please limit text to ¼ page

Strengths

- The result is a significantly improved, much better organized and written application that is likely to generate new and clinically useful results.
- The rationale and background for this work is well described and the preliminary findings support the aims.
- The inclusion of myocardial tissue sampling for assessment of remodeling and heart failure is an important addition.

Weaknesses

- The proposal would have been strengthened by including assessment of stem cell incorporation into the heart as described in reference 2 by the co-sponsor.
- Little consideration has been given to statistical methods, and discussion of outcomes and alternatives is rather limited, especially in light of the obvious interdependency of aims. What if aim 1 doesn't work?
- The proposed animal model for myocardial infarct has been questioned lately.

4. [Training Potential](#)

Please limit text to ¼ page

Strengths

- There is no doubt that the applicant will learn many new techniques because of his relative limited prior research experience.

Weaknesses

- The research plan include many molecular approaches, a new field for the applicant. Inclusion of molecular biology and cardiac development courses may help the applicant expand his critical thinking skills while performing the proposed experiments.

Additional Review Criteria

THE FOLLOWING REVIEW CRITERIA ARE NOT SCORED INDIVIDUALLY, BUT SHOULD BE CONSIDERED WHEN DETERMINING THE OVERALL IMPACT/PRIORITY SCORE.

<u>Protections for Human Subjects</u>
Acceptable Risks and/or Adequate Protections Comments (Required Unless Not Applicable): <ul style="list-style-type: none">• There are only minimal and acceptable risks associated with the study. Adequate protection plans are provided to counter any mishaps during the exercise experiments. Data and Safety Monitoring Plan (Applicable for Clinical Trials Only): Not Applicable (No Clinical Trials) Comments (Required Unless Not Applicable): <ul style="list-style-type: none">○

<u>Inclusion of Women, Minorities and Children</u> Applicable Only for Human Subjects Research
G1A - Both Genders, Acceptable M1A - Minority and Non-minority, Acceptable C3A - No Children Included, Acceptable Comments (Required Unless Not Applicable): <ul style="list-style-type: none">• Children have been appropriately excluded from the study. This is justified by the nature of the study addressing myocardial infarct which usually targets older adults.

<u>Vertebrate Animals</u>
Acceptable Comments (Required Unless Not Applicable): <ul style="list-style-type: none">• The candidate proposes to use the Meta-Mu rat strain developed in Australia. There are no concerns with animal welfare. The five points are adequately addressed. The candidate, however, should have provided justification of numbers under this section and not by simply referring the reviewer to the research plan. I strongly suggest that the five points to be addressed as five and not as seven. Additionally, conventional headings (titles) have not been used, leaving the reviewer to guesses.

Additional Review Criteria

Biohazards

Acceptable

Comments (Required Unless Not Applicable):

- No risks to the staff, and no concerns noted with any of the proposed reagents, vectors, human tissues (blood), or physical procedures (i.e. chest radiographies).

Resubmission

Please limit text to ¼ page

Comments (if applicable):

- The applicant has made efforts to address the previous criticism. The result is a much-improved application that will be a strong training vehicle to put the applicant on track to achieving his career goals of becoming an independent academic surgeon.

Additional Review Consideration

The impact/priority score should not be affected by the following considerations.

[Responsible Conduct of Research](#)

Unacceptable

Comments (Required):

- The applicant states that he will train in RCR by daily interactions with the mentor, discussions during lab meetings, and by taking the online IACUC training. This clearly will not fulfill the requirements. A more formal coursework is needed. This should address misconduct in science and other ethical issues, in addition to experimenting with human subjects training, grant writing, authorship, etc. It seems that neither the sponsors or applicant are aware of the existence of the "Survival Skills of a Scientist" course that spans over 15 sessions (weeks), and addresses all facets of RCR.

[Budget and Period of Support](#)

Recommend as Requested

Recommended budget modifications or possible overlap identified:

- The requested two years of fellowship may allow completion of the proposed work. I suggest that the applicant drops the rat model and focus on the human part of the experimental plan. This should even add some focus to this overambitious plan.

[Foreign Training](#)

Click Here to Select

Comments (Required Unless Not Applicable):

- The rat experiments are proposed in Melbourne, Australia. I am aware of three labs in the United States who have this rat strain. Moreover, I do not see what the applicant will accomplish further by going 6 months to Australia.

[Resource Sharing Plans](#)

Not Applicable (No Relevant Resources)

Comments (Required if Unacceptable):

-

Additional Comments to Applicant

Additional Comments to Applicant

[Additional Comments to Applicant](#) (Optional)

- The applicant should drop the rat experiments to bring the project to a more manageable level.

Some Top Reasons Why Grants Don't Get Funded

- Lack of new or original ideas.
- Diffuse, superficial, or unfocused research plan.
- Lack of knowledge of published, relevant work.
- Lack of preliminary data and/or experience with essential methodologies.
- Uncertainty concerning future directions (where will it lead?).
- Questionable reasoning in experimental approach.
- Absence of a sound hypothesis and clear scientific rationale.
- Unrealistically large amount of work.
- Poor training potential.
- Poor productivity.
- Mentor is not qualified, poorly funded, and/or not productive.

Didn't Make It

- Revised Application (A1)
 - One chance only
 - After that? Significantly changed application
- Consider the critique (without emotion)
- Address concerns in an Introduction
 - 1 page before Specific Aims
 - Be agreeable but not obsequious
 - Be firm but not confrontational
- Do not re-submit until all is in order
- Triaged? Do not resubmit
- Seek advice

Review of a Revised Application

- Treated as new application
- Reviewers will likely not be the same
 - Maybe 1 or 2
 - But almost always at least 1-2 new reviewers
- Reviewers only see the original critique (which includes your Abstract)
- Reviewers do not see the original (A0) application