NIH/NIA Grant Review Process

Research Centers Collaborative Network (RCCN) webinar

May 24, 2024

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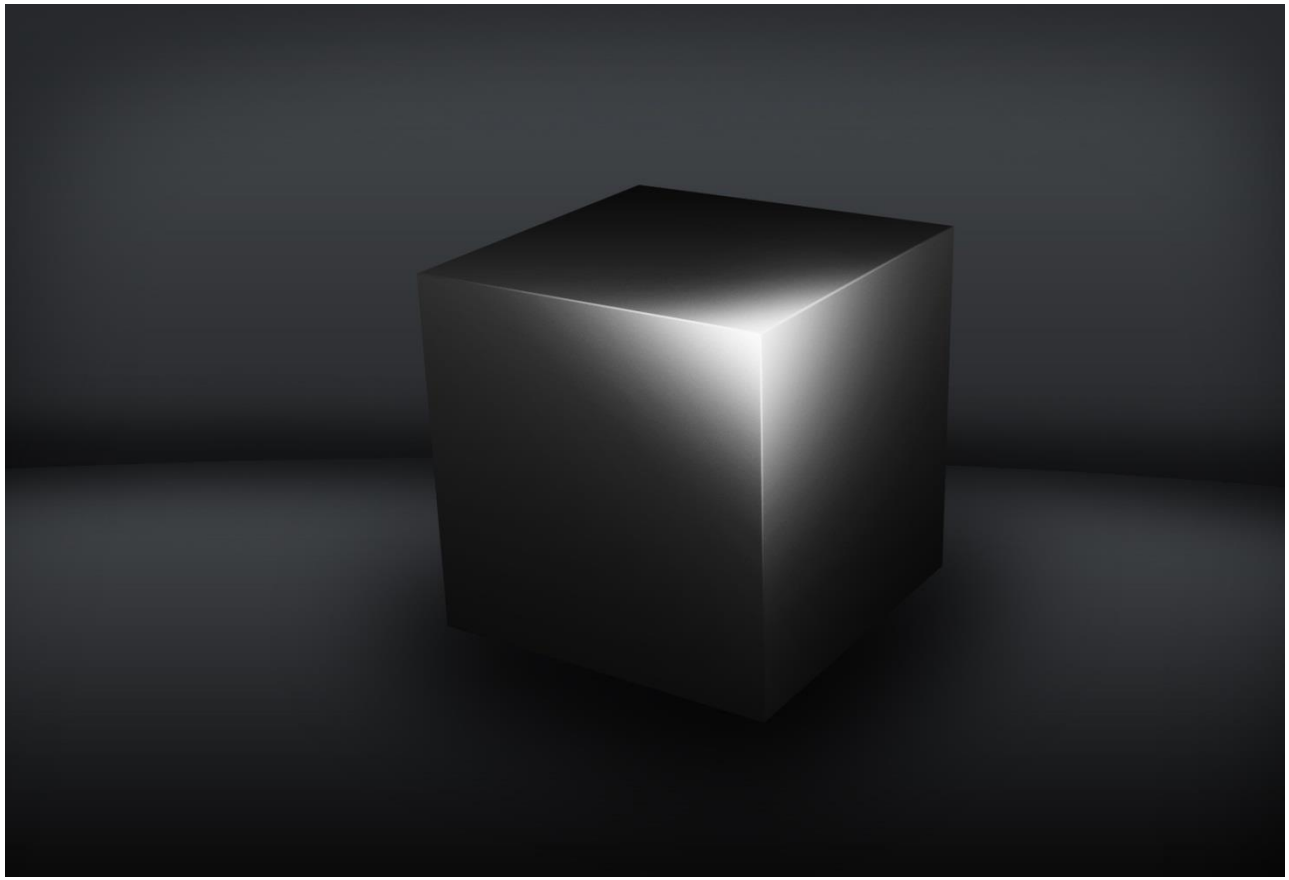
What Happens to Your Application?



NIA Standing Review Committees

AGCD 1

(K99)

SRO: Joshua Park, PhD

AGCD 2

(K01)

SRO: Dario Rodriquez, PhD

- Career Development Awards (K01, K02, K07, K08, K23, K24, K25, K99/R00)
- Clinical Trials (R01, R34)
- Conferences & Scientific Meetings (R13/U13)
- Dissertation Awards (R36)
- Research Resources (R24/U24)
- Cooperative Agreements (U01); Multi-site R01s
- Some FOAs

AGCD 3

(K08, K23, K24)

SRO: Maurizio Grimaldi, MD/PhD

AGCD 4

(K02, K07, K22, R13, K25, R36)

SRO: Raji Roy, PhD

Special Emphasis Panels (SEPs)

SEPs are constituted specifically to review applications that have been received in response to an **RFA** or other Institute specific grant mechanisms

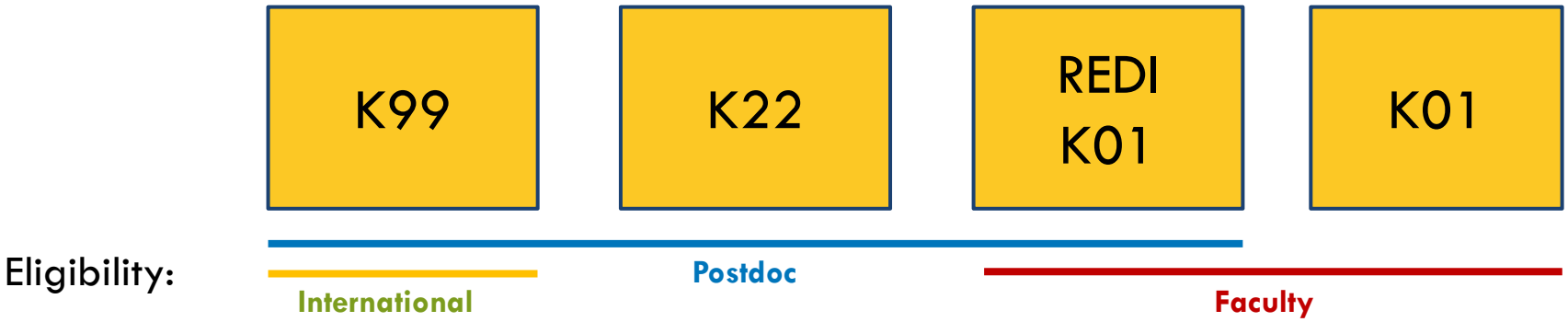
Reviewers are recruited typically for a single meeting.

The SRB runs over 100 SEPS per year.

Why seek career development (K) awards?

- They fund protected research time to learn new skillsets
- They can foster early independence
- They help attract additional funding or support

Early Career K's from NIA



- $75-100,000 in salary
- $25-50,000 in research
- 75% effort on research career development

- Require a career development plan
- Goal: career and research independence

A few other examples of K Mechanisms

- K01 Mentored Research Scientist Career Development Award
- K01 REDI Research and Mentored Entrepreneurial Immersion Career Developmental Award
- K02 Independent Research Scientist Development Award
- K05 Senior Research Scientist Award
- K07 Academic Career Development Award
- K08 Mentored Clinical Scientist Research Career Development Award
- K22 Career Transition Award
- K23 Mentored Patient-Oriented Research Career Development Award
- K99/R00 Pathway to Independence Award
- K99/R00 Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Postdoctoral Career Transition Award to Promote Diversity

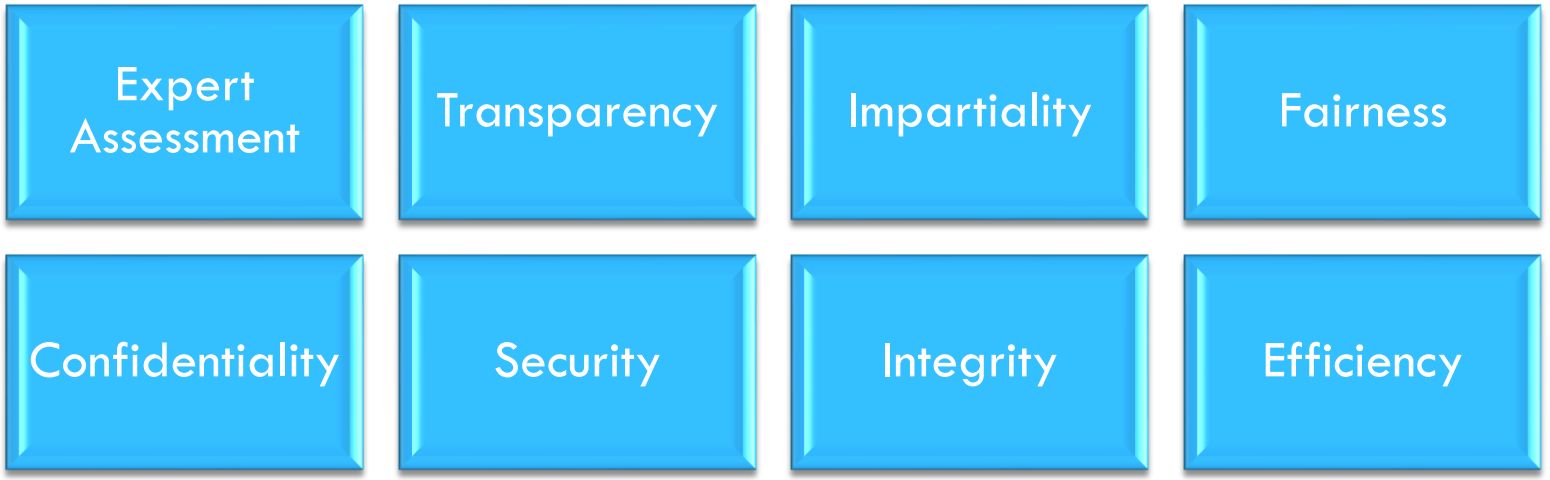
Review Process & Guidance

What is Peer Review?

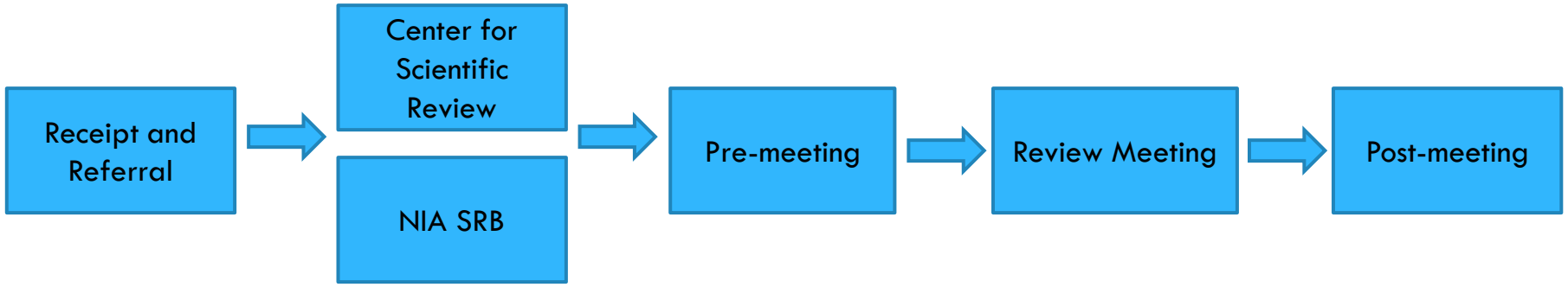
Peer Review is the cornerstone of the NIH/NIA extramural research program

- Ensures a thorough, objective and fair evaluation of the scientific and technical merit of an application (or contract proposal)
- Determines the impact on the field, providing feedback to NIH/NIA program staff and leadership for funding decisions
- Done by scientific experts in the field (peers) in a manner free from inappropriate influences
- Critical to maintain public trust in NIH-supported science

Core Values of Peer Review



Overview of the Peer Review Process



Overview – Peer Review Process

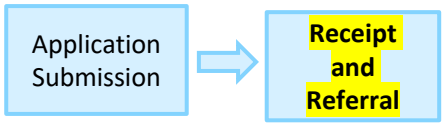
Application Submission

- Submit to Grants.gov
  - Submit at least 2 days early
  - Error-free application must be received by 5 pm local time of institution
- Errors versus Warnings
  - Errors must be addressed in order to successfully submit the application
  - Warnings should be headed as they may indicate problem leading to withdrawal post-submission
- 2 business days viewing window (check problems with application assembly)
- Track submission status in Grants. gov

Issues resulting in Potential Withdrawal

- Identical Application Under Review
- No Introduction to A1 (resubmission)
- A0 application with Introduction
- Excessive Length/Tiny Font/Format
- Disallowed Appendix Materials
- Including hyperlinks in the application (besides My NCBI in Biosketch)

Overview – Peer Review Process



- **Center for Scientific Review – Division of Receipt & Referral**
- 3 rounds of review per year
- Standard and special receipt dates
- Unsolicited or solicited applications
  - Research Projects (R01, R21, R03, etc.)
  - Multi-Component Applications and Centers (P01, U19, U54, etc.)
  - Training (fellowships, career development awards, institutional training)
  - Contracts
  - Other
- **Assignment to CSR or IC**
- ARF – to request a particular IC and/or study section

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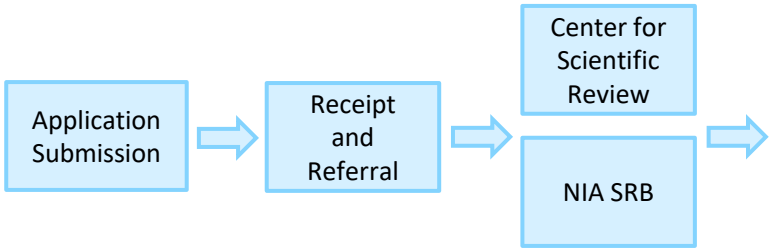

- **CSR:** applications submitted in response to most parent program announcements (mostly R01, R03, R21, fellowships)
- **NIA:** applications submitted in response to RFAs, NIA special programs, including centers and career development

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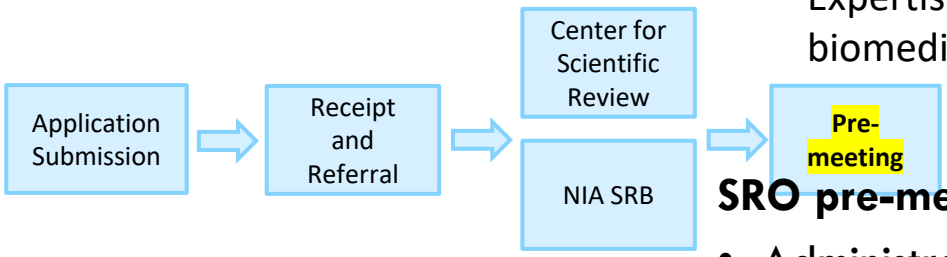


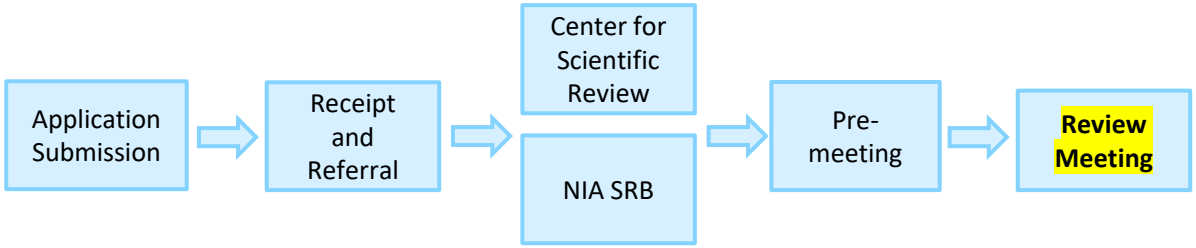
Scientific Review Officer (SRO)

- Designated Federal Official (DFO) with legal responsibility for managing the review
- Expertise in one or more areas of biomedical research

SRO pre-meeting responsibilities include:

- Administrative review of applications
- Identifying and recruiting reviewers with appropriate expertise and diversity (gender, ethnicity, seniority, geography)
- Managing conflicts of interest and assigning reviewers
- Instructing reviewers on review process, regulations and policies
- Documentation and reporting (e.g., FRN)
- The roster (**aggregate**) will be available through your Commons account 30 days before the date of review.

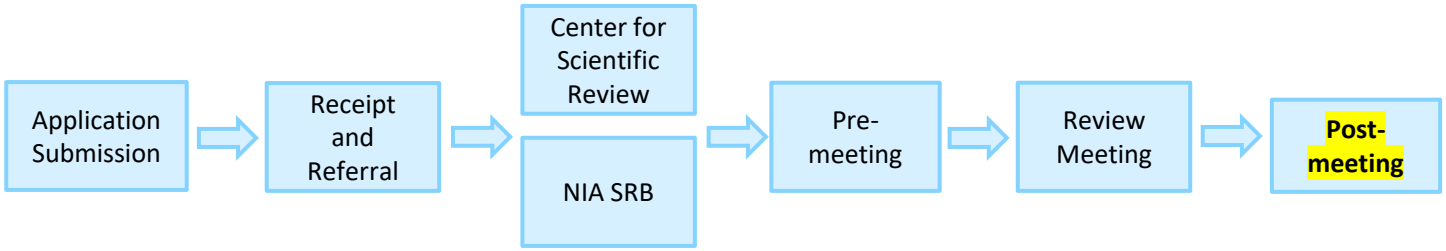
Overview – Peer Review Process



SRO meeting responsibilities:

- Review meetings can run for 1 or 2 days either (face-to-face) or as Zoom
- Managing the meeting in conjunction with Chair
- Re-emphasizing and monitoring adherence to NIH Review Policy (confidentiality, scoring, etc.)
  - Grant applications are reviewed on established review criteria
  - Assigned reviewers present their preliminary scores first and share their critiques
  - Open discussion then follows by the panel
  - Assigned reviewers re-state or modify their scores in light of discussion
  - Final scoring is conducted – "private ballot" (entire panel has to enter score)
- Monitoring the process to ensure fair, unbiased and scientifically/technically appropriate evaluation

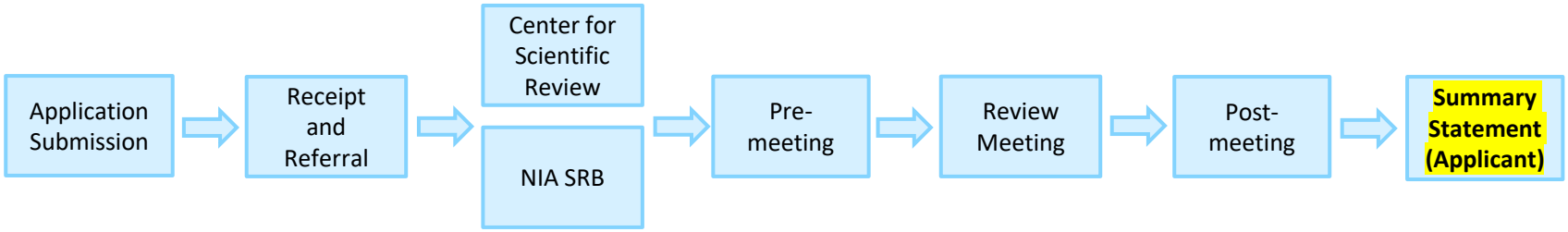
Overview – Peer Review Process



SRO post-meeting responsibilities:

- Prepare summary statement and, if needed, present information to Council (e.g., appeals)
- Initiate process for reviewer reimbursement
- Other reporting (e.g., meeting minutes)

Overview – Peer Review Process



Applicant will receive summary statement (in eRA Commons – Status Information) by 6 weeks post review or 30 days before the Advisory Council Meeting

- Summary statement = official record of the review of an application
  - Resume and summary of discussion: by SRO, based on discussion at meeting
  - Edit critiques of the assigned reviewers (where needed)
- Referred to for resubmissions and appeals

Tips from the SRO – Considerations Before Preparing a K Application

Career Development Plan

- Plan your future trajectory well!
- What is your ultimate goal?
- What additional courses and/or training are required to get you there?
- Which scientific meetings will be helpful for learning and networking?
- Define your focus – e.g., clinical or basic aspects
- Clear benchmarks at every stage would be very helpful
- Plan the time frame for writing independent research grant applications

Tips from the SRO – Considerations Before Preparing a K Application

Research Strategy

- Must be original, well conceived and not overly ambitious – check databases such as NIH RePORTER
- Do not copy mentor's research plans
- Integrate research and career development plans
- If new techniques are to be learned, state from whom, where, and how
- Timetable is very important – be realistic and plan accordingly
- Estimate start/end times for each experiment
- Nobody expects you to solve all the problems or answer all the questions

Tips from the SRO – Considerations Before Preparing a K Application

Mentor(s) and Collaborators

- Select a primary mentor based on the training you seek
- Add co-mentors and/or collaborators as needed – covering all areas required for your research training and career development
- State clearly what you know and what you propose to learn from each mentor/collaborator
- Preferably select a mentor other than your postdoctoral mentor
- Letters of recommendation should be tailored to you (experience, potential, goals)

Scored Review Criteria (K)

K critique template

1. Candidate
2. Career development plan/ Career Goals & Objectives/ Plan to provide mentoring
3. Research Plan
4. Mentors, Co-Mentor (s), Consultant (s), Collaborator (s)
5. Environment and Institutional Commitment to the Candidate

Scoring Guidance

Overall Impact:
The likelihood for a project to exert a sustained, powerful influence on research field(s) involved

Overall Impact	High	Medium	Low
Score	1 2 3	4 5 6	7 8 9

Evaluating Overall Impact:
Consider the 5 criteria: significance, investigator, innovation, approach, environment (weighted based on reviewer's judgment) and other score influences, e.g. human subjects, animal welfare, inclusion plans, and biohazards

e.g. Applications are addressing a problem of high importance/interest in the field. May have some or no weaknesses.

e.g. Applications may be addressing a problem of high importance in the field, but weaknesses in the criteria bring down the overall impact to medium.

e.g. Applications may be addressing a problem of moderate importance in the field, with some or no weaknesses

e.g. Applications may be addressing a problem of moderate/high importance in the field, but weaknesses in the criteria bring down the overall impact to low.

e.g. Applications may be addressing a problem of low or no importance in the field, with some or no weaknesses.

5 is a good medium-impact application, and the entire scale (1-9) should always be considered.

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	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

Scoring

Score impacting topics

- All criterion scores
- Vertebrate Animals Research
- Protections for Human Subjects Research
  - Inclusion of Women and Minorities
  - Inclusion of Aging across the Lifespan

Non-Score impacting topics

- Select Agents
- Resource Sharing Plans
- Authentication of key biological/chemical resources
- Budget

Rules for Success

1. Don’t be shy (communicate)
2. **Love what you are doing and be excited about it**
3. Carve a niche and focus on what you are doing
4. Be team player
5. **Network, Network, Network**
6. Read, Read, Read
7. **Publish, Publish, Publish**
8. Advancement= manuscript x collaborations
9. **Set goals and achieve them**
10. When you run into roadblocks, find a way to go around
11. **Be honest**
12. Don’t burn bridges

Tips from the SRO – Common Pitfalls

- Not reading the NOFO (aka failing to follow directions)
- Not addressing the state of the field (or its controversies) in a fair and balanced manner
- Being overly ambitious in proposed work
- Not addressing the limitations of your study followed by clearly stating alternative approaches and future directions
- Becoming lost in the weeds - missing attention to detail
- Missing attention to rigor and reproducibility
- For K's – insufficient integration of research and career development plans
- Do not think that reviewers will miss your mistakes!

Tips from the SRO – Resubmission

DO:

- Throw out your first response
- Discuss critiques and responses with mentor(s) and colleagues
- Be gracious and acknowledge reviewers' comments
- Address ALL comments/concerns by making changes or justify why you disagree
- Update and improve your application – perform more experiments, if needed

PS: Remember that just because you have responded to all critiques, you cannot automatically expect to get a fundable score because different reviewers may be reviewing your application

Tips from the SRO – Resubmission

DON'T:

- Give up on research or blame everybody else
- Take comments personally
- Attack the reviewer
- Dwell on a reviewer's error – make the point and move on
- Write a rebuttal longer than your critique
- Rush to resubmit by the next cycle

Where can I find more information?

ONLINE

- Office of Extramural Research http://grants.nih.gov
- Center for Scientific Review http://public.csr.nih.gov/Pages/default.aspx
- NIA website http://www.nia.nih.gov
- Funding Opportunity Announcements
- NIH eRA Commons https://public.era.nih.gov
- NCI publication (some items specific to NCI, but also a lot of general suggestions) http://deainfo.nci.nih.gov/extra/extdocs/gntapp.pdf
- NIAID publication http://www.niaid.nih.gov/researchfunding/grant/pages/newpiguide.aspx

PEOPLE

- Program Officer (pre-submission and post-review)
  - Training Officer
- Scientific Review Officer (post-submission until review)
- Sponsored research office at your Institution
- Colleagues at your Institution
- Mentor(s)

QUESTIONS?

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