U.S. Department of Health & Human Services

NIH Center for Scientific Review

NIH Application Review Tips and Pitfalls Discussion

Karyl B. Swartz, Ph.D.

Associate Director for Diversity
and Workforce Development
Center for Scientific Review

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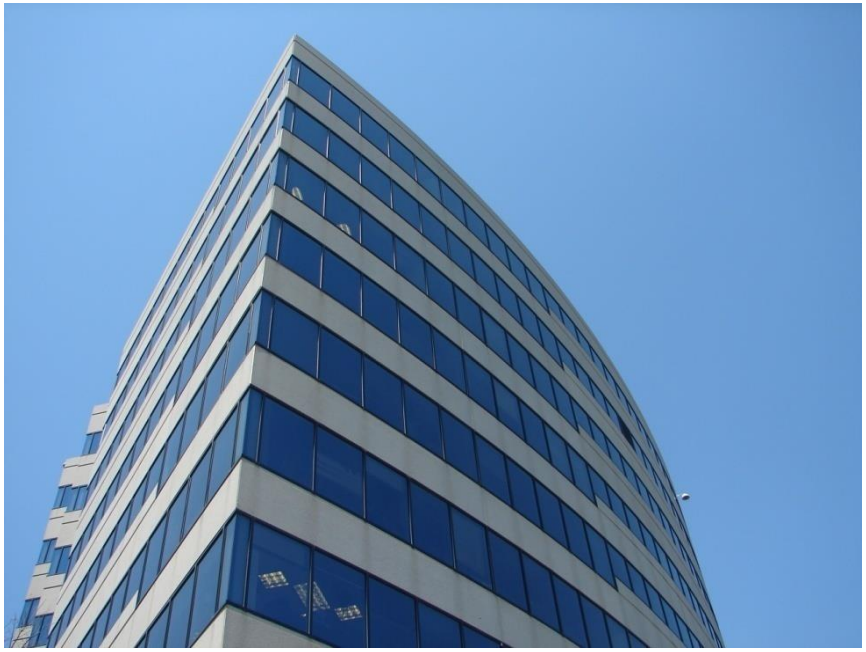
Your Application Goes to the NIH Center for Scientific Review (CSR)

Focal Point for Initial Review at NIH



- Receives all NIH applications
- Refers them to NIH Institutes/Centers and to scientific review groups
- Reviews majority of grant applications for scientific merit

CSR Study Sections: The Meeting

- Each CSR standing Study Section has ~12-22 regular members plus temporary reviewers from the scientific community
- About 70 applications are usually reviewed by each study section in 1-2 day meetings

What Happens at the Study Section Meeting

Discussion of Applications

- **Overall Impact**
  - **Core Review Criteria**
  - **Additional Criteria**

Score Applications

Budget Recommendations

Administrative Concerns

At The Meeting

Order of Review

- The average of the preliminary Overall Impact score from the assigned reviewers determines the review order
- Discussions start with the application with the best average preliminary Overall Impact score

Clustering of Review

- New Investigator R01 applications are clustered
- Clinical applications & other mechanisms (R03,R21, K) may be clustered

Not Discussed Applications

- About half the applications will be discussed
- Applications unanimously judged by the review committee to be in the lower half are not discussed

Review Criteria

5 Core Review Criteria

- **Significance**
- **Investigator(s)**
- **Innovation**
- **Approach**
- **Environment**

Each scored from 1-9

Overall Impact

Assessment of the likelihood for the project to *exert a sustained, powerful influence on the research field(s) involved*

Scored from 1-9

Additional Criteria that Contribute to Overall Impact Score

- Protections of human subjects
- Inclusions of women, minorities, and children
- Appropriate use of vertebrate animals
- Management of biohazards

Scoring Philosophy

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)

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

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

F-31 Applications

- Applicants are expected to propose a **defined research project and training plan** within the mission of the participating Institutes and Centers. The training plan should reflect the applicant's research project, which may be his/her dissertation research project, and facilitate and clearly enhance the individual's potential to develop into a productive, independent research scientist.

- The training plan should document the need for, and the anticipated value of, the proposed mentored research and training in relationship to the individual's research career goals.

- Although applicants may apply at any time, applications are encouraged once an applicant has identified a specific research project that will be undertaken in the sponsor's laboratory. This often occurs in the second year of a PhD program.

Mentored Training Experience Will Include:

- A strong foundation in research design, methods, and analytic techniques appropriate to the proposed dissertation research;
- The enhancement of the applicant's ability to conceptualize and think through research problems with increasing independence;
- Experience conducting research using appropriate, state-of-the-art methods, as well as presenting and publishing the research findings as first author;
- The opportunity to interact with members of the scientific community at appropriate scientific meetings and workshops;
- Skills needed to transition to the next stage of the applicant’s research career; and
- The opportunity to enhance the applicant’s understanding of the health-related sciences and the relationship of the proposed research to health and disease.

Review

A fellowship application has a research project that is integrated with the training plan.

The review will emphasize the applicant's potential for an independent, scientific research career, the applicant's need for the proposed training, and the degree to which the research project and training plan, the sponsor(s), and the environment will satisfy those needs.

Review Considerations

- **Overall Impact/Merit**

Reviewers will provide an overall impact score to reflect their assessment of the likelihood that the fellowship will enhance the applicant's potential for, and commitment to, a productive independent scientific research career in a health-related field, in consideration of the scored and additional review criteria.

- **Scored Review Criteria**
  - Fellowship Applicant
  - Sponsors, Collaborators, and Consultants
  - Research Training Plan
  - Training Potential
  - Institutional Environment & Commitment to Training

Training in the Responsible Conduct of Research

Important but not scored

Format - the required format of instruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups (a plan with only on-line instruction is not acceptable)

Subject Matter - the breadth of subject matter, e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics

Faculty Participation - the role of the sponsor(s) and other faculty involvement in the fellow's instruction

Duration of Instruction - the number of contact hours of instruction (at least eight contact hours are required)

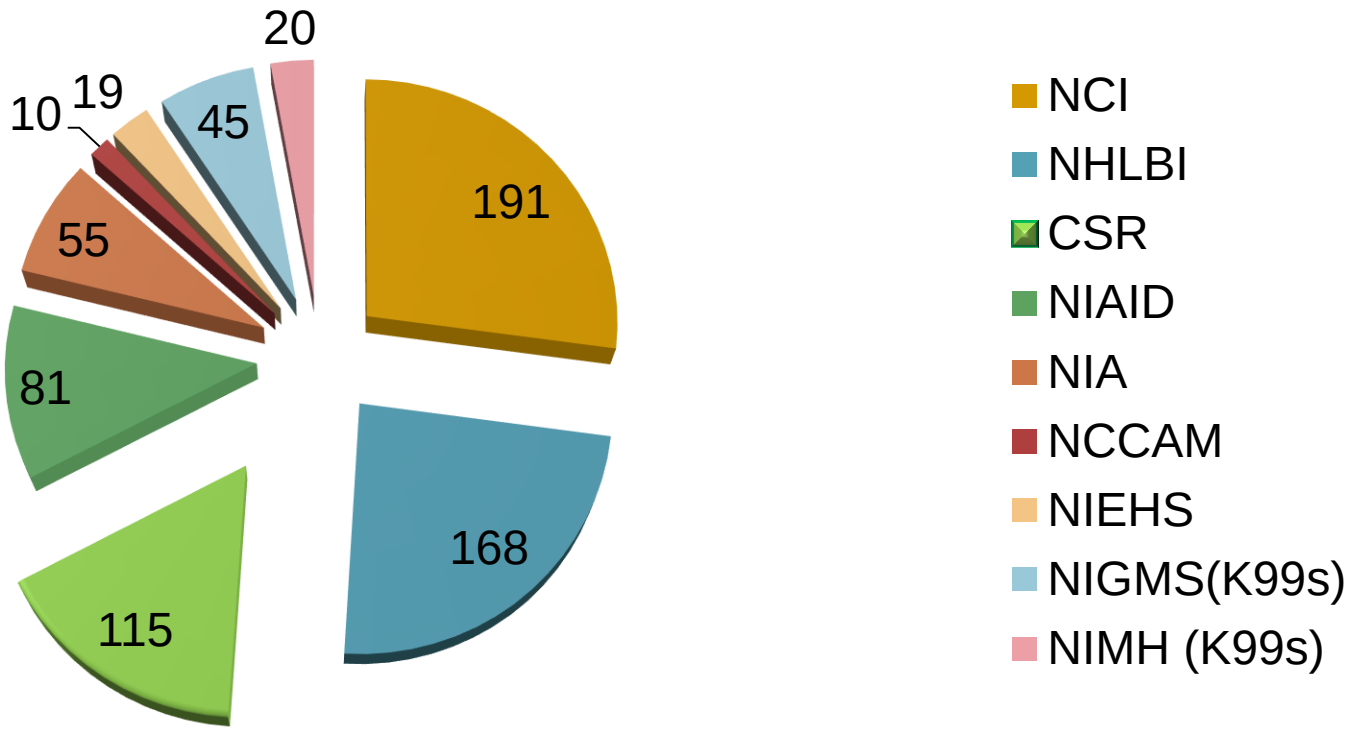
Frequency of Instruction – instruction must occur during each career stage and at least once every four years

Panel Composition

- Fellowships are reviewed by senior scientists with a track record of mentoring

- Typical Reviewers:
  - Associate Professors or higher rank
  - T32 holders, Department Chairs and Deans

K applications by Review Location



Mentored K applications

- The Mentored **Research Scientist** Development Award (K01) provides support and “protected time” (three, four, or five years) for an intensive, supervised career development experience in the biomedical, behavioral, or clinical sciences leading to **research independence**.
- The Mentored **Clinical Scientist** Research Career Development Awards (K08) program provides support and “protected time” to individuals with a **clinical doctoral degree** for an intensive, supervised **research career development** experience in the fields of biomedical and behavioral research, including translational research.
- The Mentored **Patient-Oriented** Research Career Development Award (K22) supports the career development of investigators with a **clinical doctoral degree** who have made a commitment to focus their research endeavors on **patient-oriented research**.

Reviewing K applications

- **Overall Impact**.
  - Reviewers should provide their assessment of the likelihood for **the candidate** to maintain a strong research program, taking into consideration the criteria below in determining the overall impact/priority score.

    - The Candidate.
    - Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring.
    - Mentor(s), Co-mentor(s), Consultant(s), Collaborator(s).
    - Research Plan.
    - Environment and Institutional Commitment to the Candidate.

  - Training in the Responsible Conduct of Research (not scorable)

Alignment of Review Criteria and Application: K Series

Application

Candidate Information
- Candidate Background
- Career Goals and Objectives
- Candidate's Plan for Career Development
- Training in Responsible Conduct of Research

Statement and Letters of Support
- Plans and Statement of Mentor and Co-mentors
- Letters of Support from Collaborators

Institutional Commitment to the Candidate
- Description of Institutional Environment
- Institutional Commitment to the Candidate's Research Career Development

Research Plan
- Research Strategy

Review Criteria

- Candidate
- Career Development Plan/Career Goals
- Research Plan
- Mentor(s), Co-mentor(s), Collaborator(s)
- Environment and Institutional Commitment

Rigor and Transparency in Research

To support the **highest quality science, public accountability, and social responsibility in the conduct of science**, NIH's Rigor and Transparency efforts are intended to clarify expectations and highlight attention to four areas that may need more explicit attention by applicants and reviewers:

- Scientific premise
- Scientific rigor
- Consideration of relevant biological variables, such as sex
- Authentication of key biological and/or chemical resources

Review Guidance for Scientific Premise

- Pertains to the **underlying evidence/data** for the project
- Address under **Research Plan** in K applications
- Addition to the review criteria: “Is there a strong scientific premise?”
- Specifically, has the applicant:
  - Provided sufficient justification for the proposed work?
  - Cited appropriate work and/or preliminary data?
  - Appropriately identified strengths and weaknesses in prior work in the field?
  - Proposed to fill a significant gap in the field?
  - OR has the applicant explained why this is not possible?

Review Guidance for Rigor

- Pertains to the **proposed research**
- Address under **Research Plan** in K applications
- Addition to review criteria: Are there “strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?”
- Possible considerations, if appropriate for the scientific field and research question, include plans for:
  - determining group sizes
  - analyzing anticipated results
  - reducing bias
  - ensuring independent and blinded measurements
  - improving precision and reducing variability
  - including or excluding research subjects
  - managing missing data

Applicant Guidance for Sex as a Biological Variable

NIH expectations for applicants:

- If little is known about sex differences, the application should include both sexes.
  - Sufficient numbers should be provided to inform the presence or absence of sex differences. Statistically powered comparisons between sexes may not be warranted.
  - Specific hypotheses about sex differences may not be possible.
  - Findings should be reported separately by sex in progress reports and publications.

- If sex differences are known not to exist, a strong justification should be provided if the application proposes to study one sex.

- If sex differences are known, experiments should be designed with appropriate group sizes to detect sex differences.

Review Guidance for Sex as a Biological Variable

NIH expectations for reviewers:

- As part of the Consideration of Relevant Biological Variables, assess whether the plans to address sex as a biological variable are adequate (for studies in vertebrate animals or human subjects).
- If the study involves only one sex, is this justified scientifically?
- Assess within the context of the research question and current scientific knowledge.

Reviewing Rigor and Transparency of Research:
Mentored Career Development Applications

	Applies to which applications?	Where will I find it in the application?	Where do I include it in my critique?	What should I consider?	Affect overall impact score?
Scientific Premise	All	Research Strategy	Research Plan	Is there a strong scientific premise for the project?	Yes
Scientific Rigor	All	Research Strategy	Research Plan	Are there strategies to ensure a robust and unbiased approach?	Yes
Consideration of Relevant Biological Variables, Such as Sex	Projects with vertebrate animals and/or human subjects	Research Strategy	Research Plan	Are adequate plans to address relevant biological variables, such as sex, included for studies in vertebrate animals or human subjects?	Yes
Authentication of Key Biological and/or Chemical Resources	Projects involving key biological and/or chemical resources	New Attachment	Additional review considerations	Comment on plans for identifying and ensuring validity of resources.	No

FELLOWSHIPS & CAREER AWARDS

Overall Impact:
The likelihood that the proposed training (F) or career development (K) will enhance the candidate's potential for a productive, independent scientific research career in a health-related field.

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

Evaluating Overall Impact
Consider the 5 criteria
(weighting based on reviewer's judgment):

Fs	Ks
• Applicant • Sponsor(s) • Research Training Plan • Training Potential • Institutional Environment & Commitment	• Candidate • Career Development Plan/Goals* • Research Plan • Mentor(s)** • Environment & Institutional Commitment

and other score influences, e.g. human subjects, animal welfare, inclusion plans, and biohazards

*K05 and K24: Plan to Provide Mentoring
**K02: Consultants/Collaborators

e.g. Proposes training or career development of high value/benefit for the candidate who has high potential for developing into a productive, independent scientist. May have some or no weaknesses in the criteria.

e.g. Proposes training or career development of high or moderate value/benefit for the candidate who has high or moderate potential for further development, but weaknesses in the criteria reduce the overall impact to medium.

e.g. Proposes training or career development of moderate value/benefit for the candidate who shows moderate potential. May have some weaknesses in the criteria.

e.g. Proposes training or career development of moderate or low value/benefit for the candidate who has moderate or low potential for further development. Weaknesses in the criteria reduce the overall impact to low.

e.g. Proposes training or career development of low value/benefit for the candidate who shows low potential. May have some weaknesses in the criteria.

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

Who Can Answer Your Questions?

Before You Submit Your Application

- A Program Officer at an NIH Institute or Center
- Scientific Review Officer

After You Submit

- Your Scientific Review Officer

After Your Review

- Your Assigned Program Officer

GrantsInfo: GrantsInfo@nih.gov – 301 435-0714

U.S. Department of Health & Human Services

NIH Center for Scientific Review

Jumpstart Your Career:
CSR Early Career Reviewer Program

Early Career Reviewer Program Goals

- Train and educate qualified scientists to become critical and well-trained reviewers
- Expose investigators to the peer review experience to help make them more competitive as applicants
- Enrich the existing pool of NIH reviewers

Qualifications for the Early Career Reviewer Program

- Demonstrated training and experience in the scientific areas under review as evidenced by:
  - A faculty appointment or equivalent
  - An active independent program of research
  - At least 2 senior authored research publications in peer reviewed journals in the past 2 years
- Has not previously served on a CSR Study Section
- Has not received an R01 award

ECR Service

- Attend study section meeting
- Assigned 2-4 applications as 3rd reviewer
- Write full critiques for assigned application
- Participate in no more than one study section per year and no more than twice total

How to Apply for the Early Career Reviewer Program

- Instructions are at www.csr.nih.gov/ECR

- If eligible, your name will be placed into our ECR database

- You will be invited to serve as an ECR when your expertise is needed for particular applications

Helpful Handouts

Insider's Guide to Peer Review

Insider's Guide to Peer Review for Applicants

NIH Center for Scientific Review

To help new and established applicants submit better applications, CSR asked current and recent study section chairs to share their personal insights on producing a highly competitive NIH grant application. They responded with great enthusiasm.

Don't jump too fast into writing your application: Since the most critical parts are the summary and specific aims sections, write a one-page summary page with specific aims first and share it with someone who is experienced, has their own funding or—ideally—someone who has served on a study section. If you can't wow them, start again and use the time you saved to come up with some fresh ideas.

Propose something significant: It is a real turn-off to read an application that is basically a re-hash of a previous project with a new issue. The same goes for "me too" research. Identify an area of current controversy and importance within your field. Make it something that would interest more people than you and your coworkers. Will it be important to clinicians or other investigators? Are you dealing with key questions or controversies in the field?

Good ideas don't always sell themselves: Tell me why it's important up front in the background section, and I'll be ready to roll. Tell me what's known and what isn't known and how, after you complete your studies, you'll move the field forward or answer important questions. A lot of people really are unaware of how absolutely important it is to tell the reviewer from the beginning why it's worth doing. If you're seeking an incremental advance over what's known, it's essential to justify it.

What Happens to Your Grant Application

What Happens to Your Grant Application
A Primer for New Applicants

The Center for Scientific Review (CSR) receives all NIH and some other Public Health Service grant applications. Most investigator-initiated applications for NIH funds are referred to CSR review groups.

Your application is assigned to a review group and an NIH Institute or Center

One or more CSR Referral Officers examine your application and determine the most appropriate Integrated Review Group (IRG) to assess its scientific and technical merit. Your application is then assigned to one of the IRG's study sections. A study section typically includes 20 or more scientists from the community of productive researchers. Your application also will be assigned to the NIH Institute or Center (IC) best suited to fund your application should it have sufficient merit. (More than one IC may be assigned if appropriate.)

Referral Officers follow established guidelines that define the review boundaries of each study section. These boundaries frequently overlap, and more than one study section may have the expertise to review your application. You may request in a cover note with your application that it be assigned to a particular study section or IC. The CSR referral office seriously considers such requests.

One of CSR's Referral Officers, who help assign applications to the right review groups and ICs. CSR expects to soon use text-fingerprinting software to help speed referrals.

The combined expertise of the scientists in a study section is intended to span the breadth and diversity of the science it covers. CSR may recruit temporary reviewers or secure mail reviews from outside consultants.

Checking the status of your application

As soon as your application is received and assigned to a study section, notices are posted to your online NIH Commons account. Information on the Commons and how to register is available at https://commons.era.nih.gov/commons. You may question either your study section or IC assignment by contacting the Scientific Review Officer (SRO) (previously called Scientific Review Administrator [SRA]) named in your notification or the CSR referral office (301-435-0715). It usually takes weeks to refer the thousands of applications submitted each round. If a notice is not posted in your Commons account within 3 weeks of the submission date, you should contact the referral office.

Reviewers are identified

Some of about 18,000 scientists who review NIH grant applications at CSR.

Your SRO will analyze the content of your application, check for completeness, and decide which reviewers can best evaluate it. Reviewers receive a copy of your application approximately 6 weeks before their meeting. Each application is assigned to three reviewers, and at least two of them provide written critiques. These assigned reviewers lead the discussions at the meeting.

Because of the multi-month period between submission and review, applicants often wish to submit additional materials. Before you do, you should contact your SRO to see if this is possible and what kinds of limitations apply.

NIH Grant Application Useful Web Links

NIH Grant Application
Submission and Review

Useful Web Links

Center for Scientific Review == http://www.csr.nih.gov == 301-435-1115

- NIH Peer Review Revealed Video
  http://www.csr.nih.gov/video/video.asp
- CSR's Early Career Reviewer Program
  http://www.csr.nih.gov/ECR
- The Peer Review Process
  http://www.csr.nih.gov/ApplicantResources/The-Peer-Review-Process
- Insider's Guide to Peer Review for Applicants
  http://www.csr.nih.gov/ApplicantResources/Insider/
- CSR Study Section Information – Descriptions, Rosters, Meeting Dates, etc.
  http://public.csr.nih.gov/StudySections
- More Helpful Web Links
  http://www.csr.nih.gov/links

NIH Office of Extramural Research == http://www.grants.nih.gov

- Overview of the NIH Grants Process
  http://grants.nih.gov/grants/grants_process.htm
- NIH Guide for Grants and Contracts
  http://grants.nih.gov/grants/guide/index.html
- Writing Your Application
  http://grants.nih.gov/grants/writing_application.htm
- Extramural Training Opportunities
  http://grants.nih.gov/training/extramural.htm

The OER GrantsInfo service provides information and answers to general questions on funding opportunities and grant application forms, instructions, and policies: grantsinfo@nih.gov or phone 301 435-0714.

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http://www.nih.gov

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http://www.csr.nih.gov/publications/

NIH Peer Review Information on the Web

National Institutes of Health: http://www.nih.gov

- **Office of Extramural Research**
  http://www.nih.gov/grants/oer.htm
- **Grants Policy**
  http://www.nih.gov/grants/policy/policy.htm
- **Electronic Submission**
  http://era.nih.gov/ElectronicReceipt

Center for Scientific Review: http://www.csr.nih.gov

- **Resources for Applicants**
  http://www.csr.nih.gov/ResourcesforApplicants
- **CSR Study Section Descriptions**
  http://public.csr.nih.gov/StudySections
- **CSR Rosters and Meeting Dates**
  http://public.csr.nih.gov/RosterAndMeetings

Resources

- The K Kiosk http://grants.nih.gov/training/careerdevelopmentawards.htm
- CSR K (Career Development Guidelines) http://public.csr.nih.gov/ReviewerResources/SpecificReviewGuidelines/Pages/default.aspx
- K Critique Template http://grants.nih.gov/grants/peer/critiques/k_critique_template.doc