Understanding NIH Peer Review

CPDD Grant Writing Workshop – June 17, 2015

Gerald McLaughlin, PhD
Chief, Scientific Review Branch, DER
National Institute on Drug Abuse, NIH
The Grant Review Process
Peer review is the cornerstone of the NIH research mission

YOU Initiate a Research Idea
Submit Application
YOU Conduct the Research
Allocate Funds

Center for Scientific Review
Assigns IC and Study Section

Study Section
Reviews for Scientific Merit

Institute
Evaluates for Programmatic Relevance

I/C Advisory Council
Evaluates reviews, appeals

Institute Director
Takes Final Action
Submitting an Application to NIH

• To apply as PI, your organization must give you permission to submit an application as PI; if not, consider Co-investigator or other role.

• If permitted, register early in eRA Commons as PI:
  – Almost all applications are electronically submitted
  – NIH interacts with you online through the submission process

• Follow instructions in the FOA
  – Incomplete or inconsistent applications cannot be changed after submission deadline. All parts should be consistent with the theme and scope of work proposed.
  – Seriously flawed/incomplete applications are usually rejected at Grants.gov and/or by later ‘administrative withdrawal’ by CSR/I/C Receipt and Referral, often when noticed by SRO, before peer review. Applications to RFAs also have ‘responsiveness’ evaluated by Program.
  – Even if a deeply flawed application makes it to reviewers, flaws may affect your reputation and that of the submitting organization; many universities restrict permission and/or have quality control steps internally, and earlier-than-NIH deadlines for related documents.
Application Groundwork

• New, interesting, feasible ideas are rare and are most welcome to reviewers. Investigate, read papers, think, generate many ideas, discard most, select and firm up plans for the best idea. Fortunately, even old ideas and problems have new variants and approaches. Which health-related issues are you prepared to help address? Discuss research and/or training ideas and plans with your mentors and colleagues; and have them read and re-read the application in time for you consider and edit before submitting.

• What research has NIH funded and by which Institute(s)?
  – NIH RePORTER includes all NIH funded grants since 1989
    • [http://projectreporter.nih.gov/reporter.cfm](http://projectreporter.nih.gov/reporter.cfm) and search by keyword, institute, investigator, study section for projects in a similar areas to yours
    • Surf NIH/I/C websites e.g. [http://www.nih.gov/](http://www.nih.gov/) has all I/Cs; NIDA’s home page is [http://www.drugabuse.gov/](http://www.drugabuse.gov/)

• Will the Institute(s) be interested, and what are current priorities?
  – Email, then call NIH Program staff; typically Chief-level staff of each I/C Division have contact information at websites, e.g. for NIDA at: [http://www.drugabuse.gov/about-nida/organization](http://www.drugabuse.gov/about-nida/organization) who can discuss and/or refer you to experienced specialist extramural science administrators.
Find Study Section(s), Include in Cover Letter

Include a cover letter to give CSR and I/C Referral guidance, although their decisions are seldom reversed. This cover letter is seen by CSR and SRO, not by reviewers. FIND AND SUGGEST a Study Section:

-Search CSR site: [http://www.csr.nih.gov](http://www.csr.nih.gov); the CSR study section website is among NIH’s most-visited websites. A ‘drug abuse’ search yielded 14 standing integrated CSR review panels. Among these:
  • Risk, Prevention and Intervention for Addictions: RIPA and IPTA
  • Behavioral Genetics and Epidemiology: BGES
  • Biophysical...Pharmacological..Neuroscience Fellowship: F03B
  • Drug Discovery for the Nervous System: DDNS
  • Molecular Neuropharmacology and Signaling: MNPS
  • HIV/AIDS Fellowship: AARR Fellowship SEPs
  • Behavioral Neuroscience Fellowship: F02A
-NIDA has FOA-specific SEPs, sometimes with recurring reviewers e.g. for RFAs, PARs and PASs. NIDA reviews K99/R00s and T32s.

Consider in cover letter:
• Suggesting possible study section(s)
• Suggesting Institute(s) for assignment
• Suggesting key themes/expertise in cover letter
• You can identify a few potential reviewers in your speciality area who you believe should not review your application due to an non-obvious real or perceived conflicts of interest; provide related rationale(s) (e.g. long-standing personal or professional issues with you or your mentor…document if feasible). SROs consider such potential conflicts but do not share final decisions.
• **DO NOT** suggest reviewers, this creates perceived conflicts of interest for NIH; this NIH guidance differs from that of some journals
NEW THIS Year: Modified BIOSKETCH FORMAT


**What’s most different about the new biosketch format?**

• Five-page limit, not four.
• New Section C: Contribution to Science
• Briefly describe up to five of your most significant contributions to science. For each contribution, indicate the historical background that frames the scientific problem; the central finding(s); the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and your specific role in the described work. For each of these contributions, reference up to four peer-reviewed publications or other non-publication research products (can include audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware) that are relevant to the described contribution. The description of each contribution should be no longer than one half page including figures and citations. Also provide a URL to a full list of your published work as found in a publicly available digital database such as SciENcv or My Bibliography, which are maintained by the US National Library of Medicine.
NEW BIOSKETCH FORMAT (cntd)

- Biosketch information is now within the Instructions associated with SF424 applications at [http://grants.nih.gov/grants/funding/424/index.htm](http://grants.nih.gov/grants/funding/424/index.htm) and there are somewhat different guidelines and detailed examples for:
  - General: Version C (regular applicants, and Fellowship Sponsor/Co-Sponsors)
  - Fellowship: Predoctoral vs postdoctoral
NIH Biosketch Identification

<table>
<thead>
<tr>
<th>Name</th>
<th>Position Title</th>
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**BIOGRAPHICAL SKETCH**

Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

**EDUCATION/TRAINING** (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable)

<table>
<thead>
<tr>
<th>Institution and Location</th>
<th>Degree (if applicable)</th>
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<th>Field of Study</th>
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</table>

**Updated format**

<table>
<thead>
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<th>Name:</th>
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A. PERSONAL STATEMENT

I have the expertise, leadership, training, expertise and motivation necessary to successfully carry out the proposed research project. I have a broad background in psychology, with specific training and expertise in ethnographic and survey research and secondary data analysis on psychological aspects of drug addiction. My research includes neuropsychological changes associated with addiction. As PI or co-investigator on several university- and NIH-funded grants, I laid the groundwork for the proposed research by developing effective measures of disability, depression, and other psychosocial factors relevant to the aging substance abuser, and by establishing strong ties with community providers that will make it possible to recruit and track participants over time as documented in the following publications. In addition, I successfully administered the projects (e.g. staffing, research protections, budget), collaborated with other researchers, and produced several peer-reviewed publications from each project. As a result of these previous experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic research plan, timeline, and budget. The current application builds logically on my prior work. During 2005-2006 my career was disrupted due to family obligations. However, upon returning to the field I immediately resumed my research projects and collaborations and successfully competed for NIH support.

C. Contribution to Science

1. My early publications directly addressed the fact that substance abuse is often overlooked in older adults. However, because many older adults were raised during an era of increased drug and alcohol use, there are reasons to believe that this will become an increasing issue as the population ages. These publications found that older adults appear in a variety of primary care settings or seek mental health providers to deal with emerging addiction problems. These publications document this emerging problem but guide primary care providers and geriatric mental health providers to recognize symptoms, assess the nature of the problem and apply the necessary interventions. By providing evidence and simple clinical approaches, this body of work has changed the standards of care for addicted older adults and will continue to provide assistance in relevant medical settings well into the future. I served as the primary investigator or co-investigator in all of these studies.
   a. Role of stereotactic radiosurgery in patients with more than four brain metastases. CNS oncology.
   b. Neurodevelopmental Outcomes of Extremely Low Birth Weight Infants with Spontaneous Intestinal Perforation or Surgical Necrotizing Enterocolitis. the Journal of Perinatology.

2. In addition to the contributions described above, with a team of collaborators, I directly documented the effectiveness of various intervention models for older substance abusers and demonstrated the importance of social support networks. These studies emphasized contextual factors in the etiology and maintenance of addictive disorders and the disruptive potential of networks in substance abuse treatment. This body of work also discusses the prevalence of alcohol, amphetamine, and opioid abuse in older adults and how networking approaches can be used to mitigate the effects of these disorders.

Complete List of Published Work in My Bibliography:
A. Personal Statement

My long term research interests involve the development of a comprehensive understanding of key developmental pathways and how alterations in gene expression contribute to human disease. My academic training and research experience have provided me with an excellent background in multiple biological disciplines including molecular biology, microbiology, biochemistry, and genetics. As an undergraduate, I was able to conduct research with Dr. Xavier Factor on the mechanisms of action of a new class of antibiotics. As a predoctoral student with Dr. Tanti Auguri, my research focused on the regulation of transcription in yeast, and I gained expertise in the isolation and biochemical characterization of transcription complexes. I developed a novel protocol for the purification for components of large transcription complexes. I was first author of the initial description of the Most Novel Complex. A subsequent first author publication challenged a key paradigm of transcription elongation and was a featured article in a major journal. During my undergraduate and graduate careers, I received several academic and teaching awards. For my postdoctoral training, I will continue to build on my previous training in transcriptional controls by moving into a mammalian system that will allow me to address additional questions regarding the regulation of differentiation and development. My sponsor...

... Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/collections/public/1tay8xsxteXlw5R2StTcjhq5X/?sort=date&direction=ascending

D. Scholastic Performance

Table with courses and grades
Non-compliant biosketches:

1. *SROs will instruct reviewers:*
   - Reviewers should make note of a noncompliant biosketch in the Additional Comments section of the critique template.
   - Reviewers need not consider extraneous biosketch materials included in the grant application.
   - Reviewers should not consider lists of publications beyond the acceptable four per description of a significant scientific contribution unless they are provided through a weblink to a publicly available digital database.
NEW BIOSKETCH FORMAT (cntd)

2. If the SRO or a reviewer notices a noncompliant biosketch, the following administrative note is added to the summary statement:

• ADMINISTRATIVE NOTE: During the review of this application, reviewers and/or NIH staff noted that one or more biosketches did not comply with the required format (NOT-OD-15-032). An electronic notification has been sent to the Signing Official for this application, to ensure that future applications use the correct biosketch format. NIH has the authority to withdraw such applications from review or consideration for funding.
• CSR will send an email to the Signing Official of the application organization.
Links Regarding New Biosketch


Provide feedback to [info@ncbi.nlm.nih.gov](mailto:info@ncbi.nlm.nih.gov)
After you Submit the Application

• 70% of grant applications are reviewed at the Center for Scientific Review (CSR)

• Specific mechanisms are reviewed at NIDA
  – K99/R00 Pathway to Independence Award
  – K12 Mentored Clinical Scientist Development Program Award
  – T32 National Research Service Awards (NRSA)
  – Centers, PARs, PASs, RFAs, R25, U01s

• CSR makes the initial assignments for
  • Funding IC, based on institute mission and programmatic mandates
  • Study Section, based on primary topic of application; some are reviewed at CSR, some are referred to and assigned within the Institute’s review office
Review Study Sections

• At CSR, there are 255 standing study sections defined by research topic or mechanism (e.g., fellowships).

• NIDA OEA has only Special Emphasis Panels (SEPs), recruited de novo for each review, about 100 specialty SEP reviews/year.

• The Scientific Review Officer (SRO)
  • Manages the Study Section and runs the review meeting
  • Is usually a scientist with experience in the area
  • Identifies reviewers with the correct expertise
  • Ensures fair and unbiased scientific evaluation
  • Releases average scores (10-90), writes the overall paragraph resume, may also edit critiques, releases the summary statements’ results from review meeting

The assigned SRO is your point of contact after submission through review; then the PO is your contact.
Who are the Reviewers?

- Experts in the area of science being reviewed
- Respected by their peers
- Can be from academics, NIH, industry
- They typically have broad scientific perspective
- They are impartial and without conflict of interest for the applications they review and score

The particular roster of reviewers for your application can and should be accessed via eRA Commons about 30 days before the review. If worried about expertise coverage, non-obvious conflicts of interest, or other issues, contact the SRO.
Process of NIH Reviews

• Large review meetings are primarily face to face. Telereviews, Internet Assisted Reviews (chatroom-style) and audiovisual reviews are often used for smaller reviews.

• Each application is typically assigned 3 reviewers, depending upon the complexity of the application and other variables.

• Assigned reviewers submit initial detailed critiques and 1-9 numerical scores about a week before the meeting in eCommons. Sometimes the third reviewer writes only an overall paragraph.

• Top scoring ≈50% are usually discussed from best to worst

• At the meeting:
  – Assigned reviewers present their critiques of the application
  – Open discussion among the committee
  – Each non-conflicted panel member gives a final overall impact score
## Score Descriptions

<table>
<thead>
<tr>
<th>SCORE</th>
<th>DESCRIPTOR</th>
<th>Strengths/Weaknesses</th>
<th>IMPACT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Exceptional</td>
<td><strong>Strengths</strong></td>
<td>HIGH</td>
</tr>
<tr>
<td>2</td>
<td>Outstanding</td>
<td></td>
<td></td>
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<tr>
<td>3</td>
<td>Excellent</td>
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<td></td>
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<tr>
<td>4</td>
<td>Very Good</td>
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</tr>
<tr>
<td>5</td>
<td>Good</td>
<td></td>
<td>MEDIUM</td>
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<tr>
<td>6</td>
<td>Satisfactory</td>
<td></td>
<td></td>
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<tr>
<td>7</td>
<td>Fair</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Marginal</td>
<td></td>
<td>LOW</td>
</tr>
<tr>
<td>9</td>
<td>Poor</td>
<td><strong>Weaknesses</strong></td>
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</table>
How Reviewers Evaluate an Application

- Review Criteria are listed in each FOA
- Reviewers score each of the review criteria
- Make sure you understand what each criterion is asking

<table>
<thead>
<tr>
<th>F30, F31, F32 Fellowships</th>
<th>K01 / K99</th>
<th>R01/R03/R21/U01..</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fellowship Applicant</td>
<td>Candidate</td>
<td>Significance</td>
</tr>
<tr>
<td>Sponsors, Collaborators and Consultants</td>
<td>Career Development Plan</td>
<td>Investigator(s)</td>
</tr>
<tr>
<td>Research Training Plan</td>
<td>Research Plan</td>
<td>Innovation</td>
</tr>
<tr>
<td>Training Potential</td>
<td>Mentor(s)</td>
<td>Approach</td>
</tr>
<tr>
<td></td>
<td>Co-Mentor(s)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consultant(s)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Collaborator(s)</td>
<td></td>
</tr>
<tr>
<td>Institutional Environment and Commitment to Training</td>
<td>Environment &amp; Institutional Commitment to the Candidate</td>
<td>Environment</td>
</tr>
</tbody>
</table>
Scoring Criteria – Overall Impact

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

<table>
<thead>
<tr>
<th>OVERALL IMPACT</th>
<th>HIGH</th>
<th>MEDIUM</th>
<th>LOW</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score</td>
<td>1 2 3</td>
<td>4 5 6</td>
<td>7 8 9</td>
</tr>
</tbody>
</table>

For R-type

- Addresses a problem of high importance / interest in the field. May have some or no weaknesses.
- May address a problem of high importance in the field, but weaknesses in the criteria bring down the overall impact to medium.
- May address a problem of moderate importance in the field, with some or no weaknesses.
- May address a problem of moderate/high importance in the field, but weaknesses in the criteria bring down the overall impact to low.
- May address a problem of low importance in the field, with some or no weaknesses.
What Reviewers Want

They need to understand WHAT you want to do, WHY it is important, and can YOU do it?

• Clear rationale of proposed research and methods, supported by current knowledge of literature.

• Significant and feasible project. Tables and figures are informative and readable

• All review criteria fully addressed; for U/R mechanisms, typically Significance, Innovation and Approach are incorporated within Specific Aims/Research Plan; Investigators, Biosketches; Environment, organization resources and evidence of commitment to the project. For research training mechanisms, mentor/organization support, and a strong albeit brief research project.

• No typographical or grammatical errors or inconsistencies. Errors suggest lack of attention to detail and commitment that reviewers tend to think are likely to convey to the actual research.
After the Review Meeting

- Average overall Impact Scores are released 0-3 days after the review ends in eCommons.

- A Summary Statement is generated for every application and is generally available within 30 days after a meeting.

- The summary statement includes the assigned reviewer’s written critiques regarding overall impact and each individual evaluation criterion score; occasionally comments to applicant.

- Non-discussed application summary statements have (*.*), instead of a numerical overall impact score.

- Discussed applications have:
  - Resume of the discussion at the meeting written by the SRO
  - Administrative comments regarding budget, human subjects, vertebrate animals, data sharing plans, etc.
  - Overall Impact score and percentile rank if the particular review is percentiled.
What The Overall Impact Priority Score Means

• **Priority Score**
  – The average of the panel member’s Overall Impact Score (1-9, 1 best, 9 worst) times 10.

• **Percentile**
  – Relative ranking of an application from the study section provided for applications in standing review committees
  – It is the percentage of applications with scores better than or equal to that application
  – Allows direct comparison of applications across multiple CSR study sections
  – Not all applications are given percentages; those for Institute-based reviews seldom are.
Reading the Summary Statement

- Great score? Take a deep breath and enjoy.
- Not so great score? Take a deep breath and pause
- Remember –
  - The review is not personal, it’s just the business of science
  - The comments reflect the scientific opinions of the reviewers
- Read the Summary Statement again
- Talk with your colleagues about the comments
- Talk with your Program Officer about the comments and possible next steps for this or another project.
After the Review: Evaluation by the Funding Institute

• Scientific merit
  – Is the application asking an important question?

• Program balance
  – Are other funded grants asking the same question?
  – Is the application addressing an unmet need?

• Institute mission
  – Is the topic a research priority?

• Availability of funds
  – What is the priority relative to other applications?

• Institute Director priorities
  – What directions should the I/C be moving toward?

• If funded, be attentive to guidance from NIH’s Program and Grants offices. Do and report on what is promised.

P.S.: If asked to review for NIH try to do so, although do balance with other commitments. If you are an effective reviewer, other reviewers and NIH staff notice. I/C review offices often ‘try out’ relatively junior reviewers; and CSR has an early career reviewer program: [http://public.csr.nih.gov/ReviewerResources/BecomeARreviewer/ECR/Pages/default.aspx](http://public.csr.nih.gov/ReviewerResources/BecomeARreviewer/ECR/Pages/default.aspx)
# Example of Funding Timeline

<table>
<thead>
<tr>
<th>Event</th>
<th>Dates</th>
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</thead>
<tbody>
<tr>
<td>Submission Due Date</td>
<td>Feb 5</td>
</tr>
<tr>
<td></td>
<td>Feb 12</td>
</tr>
<tr>
<td>IC/Study Section Assignment</td>
<td>Apr 8</td>
</tr>
<tr>
<td></td>
<td>Soon after</td>
</tr>
<tr>
<td>Scientific Review</td>
<td>June/July</td>
</tr>
<tr>
<td>Summary Statement Released</td>
<td>July/Aug</td>
</tr>
<tr>
<td>Advisory Council Meets</td>
<td>Sept/Oct</td>
</tr>
<tr>
<td>Earliest Start Date</td>
<td>December</td>
</tr>
</tbody>
</table>

*Up to 10 Months from Submission to Funding*
Knowledge (e.g., good websites) is Power

- **CSR Applicant Resources**
  [http://public.csr.nih.gov/ApplicantResources/PlanningWritingSubmitting/Pages/default.aspx](http://public.csr.nih.gov/ApplicantResources/PlanningWritingSubmitting/Pages/default.aspx)

- **Videos on Peer Review and Application Process**
  [http://public.csr.nih.gov/ApplicantResources/Pages/default.aspx](http://public.csr.nih.gov/ApplicantResources/Pages/default.aspx)

- **Reviewer Criteria and Templates**

- **CSR Early Career Reviewer**

- **NIDA FAQ**
  [http://www.drugabuse.gov/frequently-asked-questions](http://www.drugabuse.gov/frequently-asked-questions)