Understanding the NIH Review

Judy McShannon
Manager of Research Development

West Hall, room 228
835-6940
judith.mcshannon@nmt.edu
NIH Review Process

• Grant Application Submitted by PI
  • 1st electronic checkpoint: Grants.gov or Assist
  • 2nd electronic checkpoint: NIH eRA Commons
• Scientific Review Groups (SRGs) – first level of review recommendations based on scientific and technical merit
• National Advisory Council – second level of review consider reviews and IC’s goals and needs
• IC Director - makes final funding decisions
• Budget office – financial review
• Expect 1 year (min) from submission to award
## NIH Review Criteria

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Impact</td>
<td>Sustained, powerful influence to NIH, field, humanity</td>
</tr>
<tr>
<td>Significance</td>
<td>Problem of importance; likely to advance knowledge; effect on field of concepts &amp; methods</td>
</tr>
<tr>
<td>Investigator</td>
<td>Well trained? Credible? Appropriate for work proposed? Bring &amp; integrate experts to fill in gaps</td>
</tr>
<tr>
<td>Innovation</td>
<td>Aims, approach, methods, or topic is novel</td>
</tr>
<tr>
<td>Approach</td>
<td>Theoretical framework, exp. design, methods appropriate &amp; integrated; aims are original</td>
</tr>
<tr>
<td>Environment</td>
<td>Scientific, professional, and institutional aspects that lead to success</td>
</tr>
</tbody>
</table>
Overall Impact

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

- Spelling out benefits to field, to NIH mission, to human health
- The combined weight of the five core review criteria
- Additional review criteria (as applicable)
- Address this everywhere
  - Project Summary
  - Specific Aims
  - Research Strategy
**Core Review Criterion #1**

**SIGNIFICANCE**

- Does this study address an important problem?
- If the aims are achieved, how will scientific knowledge be advanced?
- What will be the effect on concepts or methods that drive this field?
- Address this in
  - Project Summary
  - Specific Aims
  - Research Strategy – Significance Section
Core Review Criterion #2 INVESTIGATOR

• Are the investigator(s) appropriately trained and well suited to carry out this work?
• Is the work proposed appropriate to the experience level of the PI and other researchers?
• Does the investigative team bring complementary and integrated expertise to the project (if applicable)?
• Address this in
  – Biosketch
  – Personal Statement
  – Letters of Support
Core Review Criterion #3
INNOVATION

• Does the project offer novel concepts, approaches or methods?
• Are the aims original and innovative?
• Does the project challenge existing paradigm, methodology, or technology?
• Address this in
  – Project Summary
  – Specific Aims
  – Research Strategy – Innovation Section
Core Review Criterion #4

APPROACH

• Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project?

• Does the applicant acknowledge potential problem areas and consider alternatives?

• Are the aims original and innovative?

• Address this in
  – Project Summary
  – Specific Aims
  – Research Strategy – Approach Section
Core Review Criterion #5
ENVIRONMENT

- Does the institution’s scientific environment contribute to the probability of success?
- Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements?
- Is there evidence of institutional support?
- Address in
  - Facilities and Other Resources
  - Biosketch, as appropriate
Other Review Considerations

• Human subjects (requires another section in the Research Strategy)
• Animal care and use
• Biohazards
• Select agents
• Model organism sharing plan
• Data sharing plan
• Resubmission/renewal/revision
• FOA-specific review criteria
# Align Proposal with Review Criteria

<table>
<thead>
<tr>
<th>Review Criteria</th>
<th>Sections Reviewers Look</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Impact</td>
<td>Project Summary, Specific Aims, Research Strategy</td>
</tr>
<tr>
<td>Significance</td>
<td>Project Summary, Specific Aims, Research Strategy</td>
</tr>
<tr>
<td>Investigator</td>
<td>Biographical Sketch, “preliminary studies” in Strategy</td>
</tr>
<tr>
<td>Innovation</td>
<td>Project Summary, Specific Aims, Research Strategy</td>
</tr>
<tr>
<td>Approach</td>
<td>Project Summary, Research Strategy</td>
</tr>
<tr>
<td>Environment</td>
<td>Facilities &amp; Other Resources, Biosketch(es)</td>
</tr>
<tr>
<td>Score</td>
<td>Description</td>
</tr>
<tr>
<td>-------</td>
<td>--------------</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Exceptional</td>
</tr>
<tr>
<td>2</td>
<td>Outstanding</td>
</tr>
<tr>
<td>3</td>
<td>Excellent</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Very Good</td>
</tr>
<tr>
<td>5</td>
<td>Good</td>
</tr>
<tr>
<td>6</td>
<td>Satisfactory</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Fair</td>
</tr>
<tr>
<td>8</td>
<td>Marginal</td>
</tr>
<tr>
<td>9</td>
<td>Poor</td>
</tr>
</tbody>
</table>
How to Read the Review Comments

<table>
<thead>
<tr>
<th>Criteria</th>
<th>#1</th>
<th>#2</th>
<th>#3</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Impact</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>2.6</td>
</tr>
<tr>
<td>Significance</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Investigator</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Innovation</td>
<td>4</td>
<td>3</td>
<td>4</td>
<td>3.6</td>
</tr>
<tr>
<td>Approach</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>2.3</td>
</tr>
<tr>
<td>Environment</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>2.6</td>
</tr>
</tbody>
</table>

Do the same with the comments. Cut and paste the comments from each criteria together to get a feel for what the comments are for each criteria.
Top 10 Common Reviewer Comments

#1: No **clear hypothesis or well defined goals**
- Provide focused hypothesis and objectives
- If not hypothesis driven, what is/are the overall goal(s)? Solving a problem, answering questions, developing a gizmo?

#2: **Specific Aims do not test** the hypothesis, or the Specific Aims **depend** on results from previous aims
- The best proposals have independent specific aims that address hypothesis using different approaches
- Aims should stand alone and not depend on each other
#3: Merely descriptive; **not mechanistic**
- In general, do not propose correlative or descriptive* studies. Most aren’t the Human Genome Project
- Do not propose general observations – **propose specific manipulations**, tests of hypotheses, methods development and validation, etc.

#4: **Not appropriate** for the grant mechanism
- R21 is NOT R01
- Career Development Award (K) is NOT a Research Project Grant (R)
- Bark up the right tree; contact Program Officer

*Must be high-impact, critical-need to fly with NIH
Top 10 Common Reviewer Comments

#5: The proposal is **over ambitious**
- Set **realistic goals** for budget and project period
- Limit # of aims. Leave something as the specified target of the next study.

#6: **Preliminary data** is lacking
- Include preliminary data for all aims
- Use prelim data to show capability and validate the concept
- Must propose more than just *confirming* preliminary results
Top 10 Common Reviewer Comments

#7: I’m not convinced investigator can do the experiments
  • Show what you can do; don’t propose what you can’t
  • Involve collaborators or consultants for your project
  • Show capacity-building trajectory, where appropriate

#8: Background section missing key publications and experimental findings
  • Be sure you have found key references (RePORTer tool)
  • Thoroughly describe literature, especially controversial
  • Support your views and ideas
Top 10 Common Reviewer Comments

#9: Experimental details, alternative approaches, or how data will be interpreted are inadequately described
- Don’t assume the reviewers know the methods
- Anticipate problems; provide other alternate paths
- Explain implications of (interpret) various possible results

#10: Not relevant to the mission of the Institute
- Don’t try to make your application FIT a particular IC
- Take time to find the right IC, program, and solicitation—or go elsewhere
NIH Tools

- NIH RePORTER http://projectreporter.nih.gov/reporter.cfm
- NIH-sponsored Regional Seminars
  http://grants.nih.gov/grants/seminars.htm
  http://grants.nih.gov/grants/seminars.htm#listserv
- Strategy for Obtaining NIH Funding (NIAID)
  http://www.niaid.nih.gov/researchfunding/grant/strategy/Pages/default.aspx
- Podcasts and transcripts of Videos
  http://grants.nih.gov/podcasts/All_About_Grants/