Understanding the NIH Review

Judy McShannon

Manager of Research Development

West Hall, room 228 835-6940

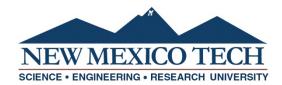
judith.mcshannon@nmt.edu



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

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

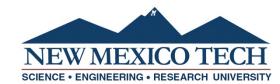


Overall Impact

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



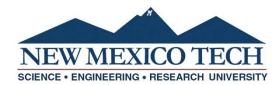


Core Review Criterion #1 SIGNIFICANCE

- 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



Significance



Core Review Criterion #2 INVESTIGATOR

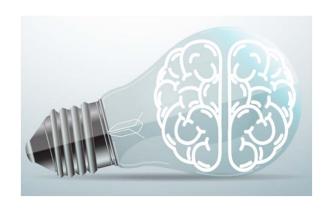
- Are the investigator(s) appropriately trained and well suited to carry out this work?
- Is the work proposed appropriate to the experience level of the PI and other researchers?
- Does the investigative team bring complementary and integrated expertise to the project (if applicable)?
- Address this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





Core Review Criterion #3 INNOVATION

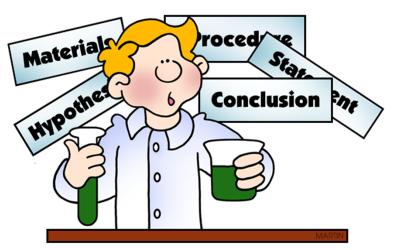
- Does the project offer novel concepts, approaches or methods?
- Are the aims original and innovative?
- Does the project challenge existing paradigm, methodology, or technology?
- Address this in
 - Project Summary
 - Specific Aims
 - Research Strategy Innovation Section





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

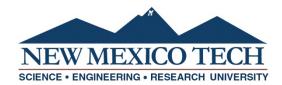




Core Review Criterion #5 ENVIRONMENT

- 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
 - o Biosketch, as appropriate

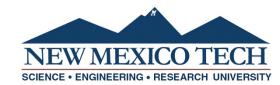




Other Review Considerations

- 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

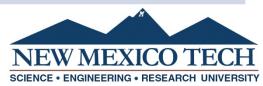




Align Proposal with Review Criteria

Review Criteria	Sections Reviewers Look		
Overall Impact	Project Summary Specific Aims Research Strategy		
Significance	Project Summary Specific Aims Research Strategy		
Investigator	Biographical Sketch "preliminary studies" in Strategy		
Innovation	Project Summary Specific Aims Research Strategy		
Approach	Project Summary Research Strategy		
Environment	Facilities & Other Resources Biosketch(es)		

NIH Scientific and Technical Review Scores						
Score	Description	Additional Guidance on Strengths/Weaknesses				
High Impact						
1	Exceptional	Exceptionally strong with essentially no weaknesses				
2	Outstanding	Extremely strong with negligible weaknesses				
3	Excellent	Very strong with only some minor weaknesses				
Medium Impact						
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				
Low Impact						
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				



How to Read the Review Comments

Criteria	#1	#2	#3	Average
Overall Impact	3	3	2	2.6
Significance	2	2	2	2
Investigator	1	2	3	2
Innovation	4	3	4	3.6
Approach	2	2	3	2.3
Environment	2	2	4	2.6

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.







#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

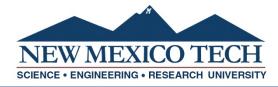


#3: Merely descriptive; not mechanistic

- 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

#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



#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



#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

- Glossary http://grants.nih.gov/grants/glossary.htm
- NIH RePORTER http://projectreporter.nih.gov/reporter.cfm
- Success Rates http://report.nih.gov/success_rates/index.aspx
- NIH-sponsored Regional Seminars
 http://grants.nih.gov/grants/seminars.htm
 http://grants.nih.gov/grants/seminars.htm#listserv
- NIH Guide—announcements, solicitations, etc. http://grants.nih.gov/grants/guide/
- 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/

