U.S. Department of Health & Human Services

NIH Center for Scientific Review

CSR Advisory Council Workgroup: Simplifying Review Criteria

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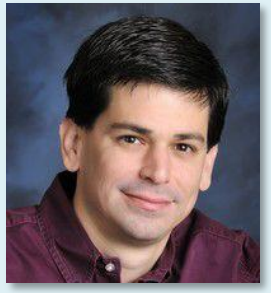

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Background and Charge

- External feedback and CSR/OER concerns that the review criteria have become too numerous and complex
  - reduced focus on scientific merit
  - increased reviewer burden

Charge

Recommend changes to research project grant review criteria that will improve review outcomes and reduce reviewer burden.

Scope

- RPG criteria with focus on RO1/R21s
- Initial focus on non-clinical trials applications

Process - Workgroup

I. Meeting 1

- WG members reviewed current review criteria, identified concerns, brainstormed solutions
- 3 smaller groups formed with the charge to turn ideas into proposals
- Each of these smaller groups prepared a written report regarding their recommendations, which also included suggestions for the review template

II. Meeting 2

- 3 small group reports were reviewed and identified areas of consensus

III. Issued Blog inviting ideas

IV. Interim report

V. Next Steps

Additional Input

- Background from OER, and informal consultations with NIH Office of the General Counsel
  - Public Health Service Act, 42 U.S.C. 289a "Peer Review Requirements" and other laws prescribe review criteria that include Significance, Investigator(s), Innovation, Approach and Environment.
  - Interpretation of prescribed review criteria is up to NIH
  - Matters of scoring are matters of NIH policy

- Ideas from the external scientific community
  - *Review Matters* Blog was released on Feb 27, 2020
  - Re-posted on OER's *Open Mike*
  - Over 8000 unique page views
  - Generated over 400 comments and emails from the extramural community

Feedback from the Community

Many thoughtful replies

- Many comments concerned review practices outside of review criteria
- Often stated
    - *Innovation* is problematic
    - *Approach* is important but reviewers nitpick
    - *Significance* is important and misunderstood
    - *Investigator* matters but is misused
        - compressed range
        - contributes to bias
    - *Environment* is a “low impact” criterion

One clear message: An overwhelming majority of respondents felt that additional review considerations such as inclusion plans, resource sharing plans, budgets, resource authentication plans, etc. should be reviewed administratively by NIH.

Recommendation 1:
Reorganize review criteria to focus on key questions.

- Reorganize the five core review criteria into three factors, “Importance of the Science”, “Feasibility and Rigor”, and “Investigator(s) and Environment”.

- Intention is to focus reviewers’ attention on the big picture questions that should drive scores
  - *Should it be done*? → Importance of the science
  - *Can it be done well?* → Feasibility and rigor
  - *Will it be done?* → Investigators and environment

- Applications to receive three factor scores plus an Overall Impact score.

Recommendation 2:
Define each criterion and factor conceptually.

- Provide a definition of each criterion to explain the concept, rather than list a set of questions to be answered.
- Select questions may be useful

Recommendation 3:
Alter templates to focus reviewer attention on score driving factors.

- Remove headers for “Strengths” and “Weaknesses” below each scored criterion
- Instead provide headers for “Major Score-Driving Factors” and “Minor Points (optional)”
- Bullets or no bullets?
  - “Using sentences or short narratives, explain the points that determine your score, clearly and concisely”
  - Future web-based templates will offer new ways to encourage brief, informative content

Recommendation 4:
Clarify reviewer responsibility for evaluating the budget.

Reviewers should judge whether the proposed budget is appropriate given the proposed work.

- Drop-down menu with 3 options
  - ❑ Budget is appropriate to support the scientific activities proposed.
  - ❑ Budget appears excessive. Further justification is needed.
  - ❑ Budget appears inadequate and raises concerns about project feasibility.

An optional comments field could capture any specific concerns.

Recommendation 5:
Relieve reviewers of responsibility for most "additional review considerations".

- Biohazards
- Applications from Foreign Organizations
- Select Agent Research
- Resource Sharing Plans
- Authentication of Key Biological and/or Chemical Resources

Rationale: Asking reviewers to evaluate these considerations dilutes their attention to scientific merit. It also risks inadequate review of the considerations.

Recommendation 6:
Convene an additional workgroup for review criteria for clinical trials applications.

- Intent is to implement the same principles of relieving reviewers of responsibility for some aspects of the review.
- Recognizing that there are some unique considerations with reporting requirements for clinical trials, additional input from a workgroup with this specific focus and expertise is needed.

Example – Factor 1

- **Importance of the science (scored).** Assess how important it is to accomplish the proposed science. Try to evaluate the importance of this application not simply with respect to other very similar applications, but in the broad context of current scientific challenges and opportunities. Base your judgment of *Importance* on your evaluation of the application's *Significance* and *Innovation*.

- Using sentences or short narratives, explain the points that determine your score, clearly and concisely. Evaluate the most important strengths and weaknesses of the application with respect to *Importance of the Science.*

Defining Significance and Innovation

Significance (not scored):

Evaluate the scientific value of the knowledge likely to be gained through the proposed studies. Consider the impact of the facts it may establish, the methods, models and concepts it may develop or discredit, how that knowledge may shape future science, understandings of basic biology, physiology, or pathophysiology, disease and its prevention or treatment. *Significance of the science must be distinguished from the significance of the disease, biological or physiological process, or broad scientific problem that frames it.*

Innovation (not scored):

Evaluate the novelty and creativity of the ideas, methods, techniques, resources or other scientific products… Consider the extent to which novel ideas, data, and methods, etc. would be valuable in advancing biomedical science or in enhancing health.

Implementation of Recommendations – Overall Impact

Overall Impact Score

Judge the overall scientific and technical merit of the application. Considering the importance of the science, the feasibility and rigor of the proposed approach, and the capabilities of the scientists involved, assess the likely contribution of the project to advancing fundamental knowledge about the nature and behavior of living systems, or the application of that knowledge to enhancing human health. Write a clear, concise paragraph that explains the basis for your score. Identify and weigh the most important strengths and weaknesses of the application.

Next Steps

- Obtain CSRAC advice
- Further consideration of blog comments and emails
- Trans-NIH consultation and input
  - OER, OGC, the ICs and other NIH entities
- Need to evaluate criteria for other types of funding mechanisms
  - Clinical trials
  - Training grant applications
  - SBIR/STTR

Discussion