Proposed New Framework for Peer Review Criteria

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NIH Advisory Council to the Director
November 3, 2022
Proposed New Peer Review Framework

- Background
- External input and timeline
- Main recommendations of external working group, NIH-proposed new framework
- Next steps and discussion
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NIH’s Unique, Two-Level Peer Review System

- First-level peer review has a **singular, important goal**: provide expert advice to the NIH on the scientific and technical merit of grant applications.

**Diagram:**

1. First Level of Review
   - Study Section or SEP
   - Evaluation of Scientific Merit

2. Second Level of Review
   - IC Advisory Council
   - Review of first level peer review outcomes, recommendation for funding, advice on programmatic priorities
Two main drivers for rethinking criteria

- Expansion of reviewer duties beyond goal of first-level scientific peer review
- Reducing bias in the peer review process
Expansion of reviewer duties beyond goal of first-level scientific peer review

What it means:
• First-level peer review has a singular, important goal - to provide expert advice to the agency on the scientific and technical merit of grant applications. The agency relies on the collective scientific expertise of the study section to identify potentially high impact research.

• Over time, incrementally, NIH has asked scientific peer reviewers to take on other functions – administrative checks, policy compliance, culture change, and accountability.

What are the consequences?
• Reviewer burden and bandwidth issues – can affect quality of scientific input
• Reviewer recruitment – administrative burden can be a disincentive to serve
Date: Friday, March 4, 2022 at 12:32 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <lawrence.tabak@nih.gov>
Cc: "Byrnes, Noni (NIH/CSR) [E]" <byrnesn@csr.nih.gov>
Subject: [EXTERNAL] Peer Reviewers Face Minor Frustrations that Dissuade Participation in Peer Review

Dear Dr. Tabak,

I feel a responsibility to participate in peer review to support biomedical research and my colleagues in the research community. Minor inconveniences have made the process increasingly frustrating.

..........

Peer reviewers now must complete review forms with an ever-expanding list of review elements. The review form for a recent review had 20 elements! Would it not be possible for paid staff to check the applications for routine elements rather than rely on volunteer reviewers to screen applications for sections that are largely boilerplate? Shouldn't the precious time of volunteer reviewers be focused on critical evaluation of the science?

I sincerely hope you will address the increasing demands and frustrations that have crept into NIH peer review. I worry that experienced peer reviewers will decide the frustrations are just too much.
Reducing Bias in the Review Process

NIH and CSR leadership hear community concerns about reputational bias in peer review, include calls to move Investigator/Environment to administrative review (not doable)

- Content analyses from feedback phase of CSR’s Simplifying Review Criteria and CSR’s Strategic Plan draft

- Direct communications to NIH/CSR leadership e.g. ACD member J. Hildreth to F. Collins/L. Tabak – did testimonial in CSR Bias Training video; Byrnes NIMHD Sept 2022 Council discussion, feedback at 2022 CSR annual summer incoming chair orientations

- **CSR Advisory Council Working Group on Bias Training** – included those with expertise in bias training, investigators from HBCU/MSIs, lower resourced and “middle of the country” state institutions, focused in largely on reputational bias as content for CSR’s Bias Awareness Training module for reviewers –training very well-received ([Reviewer Survey Results](#)), scenarios resonated with reviewers
Reducing Bias in the Review Process

Restructuring review criteria is one of several concurrent CSR initiatives to reduce bias, increase fairness to facilitate the identification of the strongest, highest-impact research.

CSR “Anonymization” Study:
- No effect on scores of Black applicants
- Worsens scores of white applicants (significant, small effect size)
- ~20% of the time, reviewers could correctly identify the applicant

Two takeaways:
- Isolating the effect of race in the peer review process is challenging due to secondary, linked variables (e.g. institution “prestige”) all tied to racial disparities in opportunity/access.
- Findings support review approaches that diminish the role of PI identity

https://public.csr.nih.gov/AboutCSR/Address-Bias-in-Peer-Review
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In January 2020, convened CSR AC Working Group

- **Charge**: Recommend simplified review criteria to improve quality of review through a refocus on scientific merit assessment

- **Scope**: RPGs, with a focus on R01s/R21s

- **Group decided to start with less complex non-CTs** (~90% of NIH applications), then a second WG with additional expertise was formed to consider CTs.

- Obtained OGC guidance regarding legal and regulatory guardrails - 5 review criteria *(Significance, Investigators, Innovation, Approach, Environment)* are defined by PHS C.F.R. 52.h.8 – NIH has discretion about how to interpret or group them, and on all matters of scoring.
CSR AC Working Groups: Simplifying Review Criteria

CSR Advisory Council

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Review Matters and Open Mike blogs – Feb 2020
- > 9000 page views; ~400 comments received
- Content analysis of feedback provided to Working Groups

Main themes of content analyses:
- Innovation – confusing – remove or group with significance
- Investigator/Environment – highly subjective, open to bias, remove
- Additional review considerations - remove to administrative review by NIH
- Approach – emphasize feasibility and rigor; reduce emphasis on minutiae
External input gathering/process timeline

Jan 2020 – Mar 2020: WG1 (non-CT) – 7 virtual meetings

Mar 2020 - Interim report presented/discussed publicly at full CSR AC (video, slides)

Sept 2020 – Feb 2021 - WG2 (CT) – 4 virtual meetings (Sept 2020-Feb 2021)

Mar 2021: Combined WG1/WG2 recommendations presented and approved by full CSRAC council (video, slides)

Apr 2021: Final report of combined CSR Advisory Council WGs’ recommendations published
NIH process/timeline

July 2021 – Mar 2022: Trans-NIH Extramural Activities Working Group formed a committee -- further develop CSR AC recommendations

Mar 2022 – Status update [Byrnes] at public CSR Advisory Council March meeting [videocast]

April 2022 – NIH modifications/recommendations presented to NIH steering committee and leadership – approved new, 3-factor based framework for peer review

Sept 2022 – Status update [Byrnes] at public CSR Advisory Council September meeting [videocast]
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Major recommendations of CSRAC for new peer review framework

Reorganize the current five scored review criteria into three factors:

- Should it be done? → **Factor 1: Importance of the Research** (Significance and Innovation) – *scored, affects overall impact score*
- Can it be done well? → **Factor 2: Feasibility & Rigor** (Approach) – *scored, affects overall impact score*
- Will it be done? → **Factor 3: Investigator & Environment** (Investigator, Environment) – *scored, affects overall impact score*

Plus: Relieve reviewers of responsibility for most “additional review considerations” and more

Detailed Report: [CSR Advisory Committee Working Group Recommendations for Simplifying RPG Review Criteria](#)
For NIH/CSR: An opportunity to address potential bias in Investigator/Environment criteria

• Literature on bias in evaluations from multiple fields indicates that clear, specific review criteria can reduce bias

• For RPGs, the goal is to consider Investigators and Environment in the context of the research project, i.e.
  • Evaluation of investigator’s **expertise and training** to carry out the project, not the reviewer’s opinion about the investigator based on pedigree, reputation or lack thereof.
  • Evaluation of the environment’s **resources** for success of the project, not the reviewer’s opinion about the quality, prestige or lack thereof of the institution.

• But reviewers tend to veer off course – current peer review structure gives them latitude to do that, i.e. score [1-9] Investigator(s) and Environment and write bulleted, open-ended narrative in strengths and weaknesses
New Review Framework – CSRAC recommendations

Proposed NIH-driven modifications

**CSR Advisory Council WG Recommendations:** 3-factor system (all factors affect overall impact score)

Factor 1: Importance of the Science (Significance, Innovation) - scored
Factor 2: Rigor and Feasibility (Approach, Innovation) - scored
Factor 3: Investigators and Environment (Investigator, Environment) – scored

**Proposed NIH modifications:** 3-factor system (all factors affect overall impact score)

Factor 1: Importance of the **Research** (Significance, Innovation) - scored
Factor 2: Rigor and Feasibility (Approach, **Innovation**) – scored
Factor 3: Investigators and Environment **Expertise and Resources** (Investigator, Environment) – scored **not scored**

Drop-down “appropriate” or “gaps identified” – gaps in expertise or resources must be explicitly identified and should affect overall impact score

Plus minor changes to additional review criteria/considerations
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Ongoing activities, next steps

Ongoing efforts:
• Trans-NIH committee incorporating rigorous CT RPG reviews into proposed framework
• Incorporation of Plan to Enhance Diverse Perspectives (PEDP) into RPG framework

Next steps:
• Public rollout of proposed NIH changes for RPG review
• Gathering of community input via RFI in Nov/Dec 2022
• Full discussion at Dec ACD

For your awareness – up next:
CSR Advisory Council WG on NRSA Fellowship review issued recommendations in Sept 2022 (slides, videocast) - under consideration by NIH