CSR's Initiatives to Strengthen Peer Review

Upcoming changes in the peer review of NIH Research Project Grants (RPGs) and Individual Fellowships (Fs)

Noni Byrnes, Ph.D. Director Center for Scientific Review

National Advisory Child Health and Human Development Council September 4, 2024



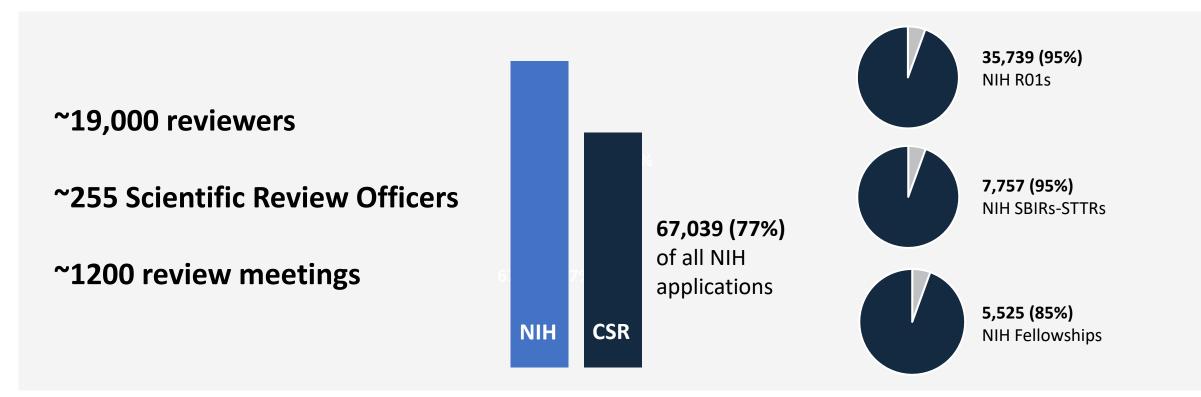
CSR's Mission

To ensure that NIH grant applications receive fair, independent, expert, and timely scientific reviews - free from inappropriate influences - so NIH can fund the most promising research.





CSR Snapshot (Fiscal Year 2024 numbers)

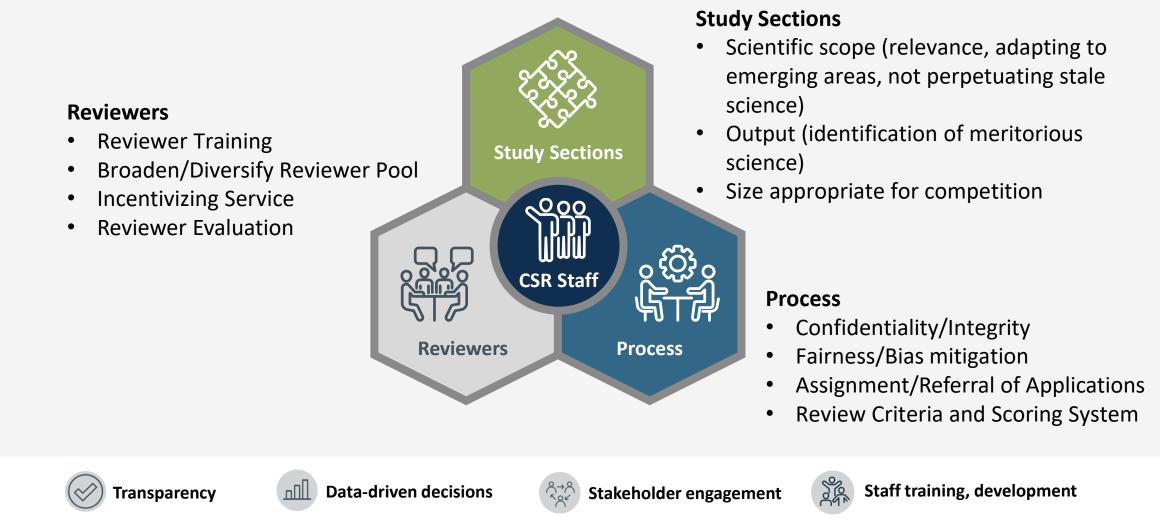


Plus, CSR reviewed 164 special initiatives, such as:





Since 2019, CSR's Strategic Framework: Quality of Peer Review



Core Operating Principles

Center for

Scientific Review

Capacity building for the future of NIH peer review

Establishing a strong foundation in communications, training and data analytics

Office of Communications & Outreach [2020]

Office of Training & Development [2022]



Division of Planning, Analysis and Information Management [2021]

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Fostering engagement, transparency, easier access to information for the scientific community

Centralized, multimedia training resources for study section chairs, reviewers, SROs Centralized operation to provide analytics, tools to support datadriven decision-making

These resources have allowed CSR to develop and implement numerous initiatives to promote fairness, integrity and quality in the NIH peer review process

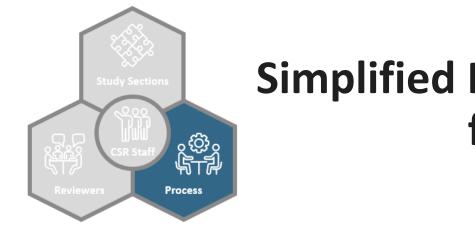


Some Examples

CSR's initiatives to promote fairness, integrity and quality in peer review

- 1) Trainings on Bias Awareness/Mitigation and Review Integrity for reviewers now mandatory for all NIH reviewers prior to participation in study sections
- 2) Reporting avenue for concerns with the fairness of the review process [reportbias@csr.nih.gov]
- **3)** Broadened the pool of reviewers in multiple dimensions to ensure fresh perspectives, reduce undue influence or scientific gatekeeping
- 4) Simplified review framework for most NIH Research Project Grants
- 5) Revised review criteria (and application) for Individual Fellowship Awards





Simplified Review Framework (SRF) for most RPGs



Main Goals of Simplifying Review Framework

- Refocus first-level peer review on its singular role of providing advice to the agency regarding the scientific/technical merit of grant applications
 - Reframes criteria to focus reviewer attention on 3 key questions
 - Removes distractions of certain administrative compliance items
- Mitigate reputational bias [e.g. institutional reputation, investigator pedigree] in the peer review process
 - Refocuses evaluation of investigator and environment to be within the <u>context of the</u> proposed research project

Facilitates the overarching goal of peer review: identification of the strongest, potentially highest-impact research



RPG Review: 5 Criteria \rightarrow 3 Factors

Applications submitted before January 25, 2025

Overall Impact Score based on 5 criteria

- Significance scored 1-9
- Investigator(s) scored 1-9
- Innovation scored 1-9
- Approach scored 1-9
- Environment scored 1-9

Applications submitted on or after January 25, 2025

Overall Impact Score based on 3 Factors

- Factor 1: Importance of the Research (should it be done?)
 - Scored 1-9
- Factor 2: Rigor and Feasibility (can it be done well?)
 - Scored 1-9
- Factor 3: Expertise and Resources (are the expertise and resources in place to do it?)
 - Evaluated as "appropriate" or "additional expertise/resources needed"; if additional needs are identified, comments are required
 - Gaps in expertise and/or resources should affect Overall Impact score

*Applies to most RPGs: R01, R03, R15, R16, R21, R33, R34, R36, R61, RC1, RC2, RC4, RF1, RL1, RL2, U01, U34, U3R, UA5, UC1, UC2, UC4, UF1, UG3, UH2, UH3, UH5, R21/R33, UH2/UH3, UG3/UH3, R61/R33



RPG review changes based on extensive input from scientific community

Jan 2020 – April 2021: Working Groups of CSR Advisory Council

- Initial input gathering through blog posts (Open Mike, Review Matters), >400 comments, content analyses
- Convened two CSR Advisory Council working groups with overlapping membership to consider non-clinical trials (~90% of NIH applications) and clinical trials RPGs.
- Legal and regulatory guardrails provided: 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. Working groups held 11 virtual meetings to develop framework and recommendations
- Full CSR Advisory Council approval of working group recommendations, publication of report

July 2021 – Sept 2022: NIH leadership input

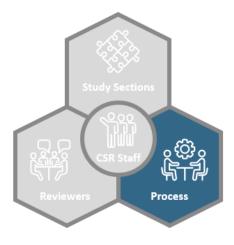
• Internal NIH discussions, input/modifications to the framework, approval by IC and NIH leadership

Dec 2022 – March 2023: Public Request for Information (RFI)

- Over 800 responses, from individuals, societies. Majority of respondents were very supportive not surprising given that these changes were developed with significant, sustained input from the broader extramural scientific community
- Minority felt that Factor 3 should be scored; smaller minority suggested blinded reviews
- Most recommended that CSR develop strong training resources to socialize the change for reviewers, study section chairs, and scientific review officers

Oct 2023: NIH announced the launch of SRF (NOT-OD-24-010), effective Jan 2025 receipt dates





Improving the Review of Individual Fellowship Applications



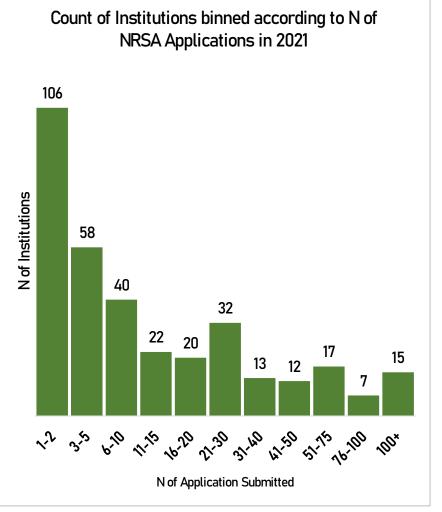
Goal: Optimize the identification and training of the most promising scientists of the next generation



- **Concerns from the scientific community** that NIH is potentially leaving out very promising research scientists of the future because of a review process for NRSA fellowships that favors elite institutions, and senior, well-known sponsors
- CSR's data analysis of >6,000 applications supported those concerns
 - A small number of institutions submit a majority of F applications
 - Applications from institutions that submit more Fs have better review outcomes
 - Review outcomes for fellowships improve as the rank of the sponsor increases

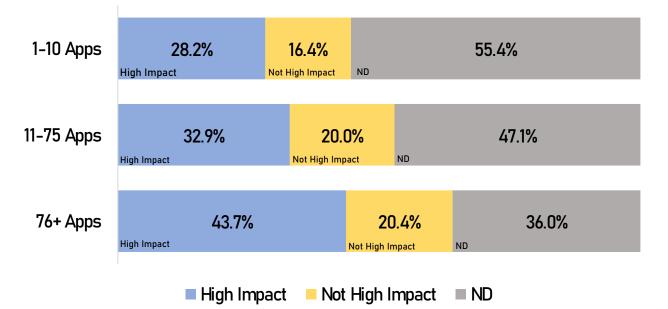


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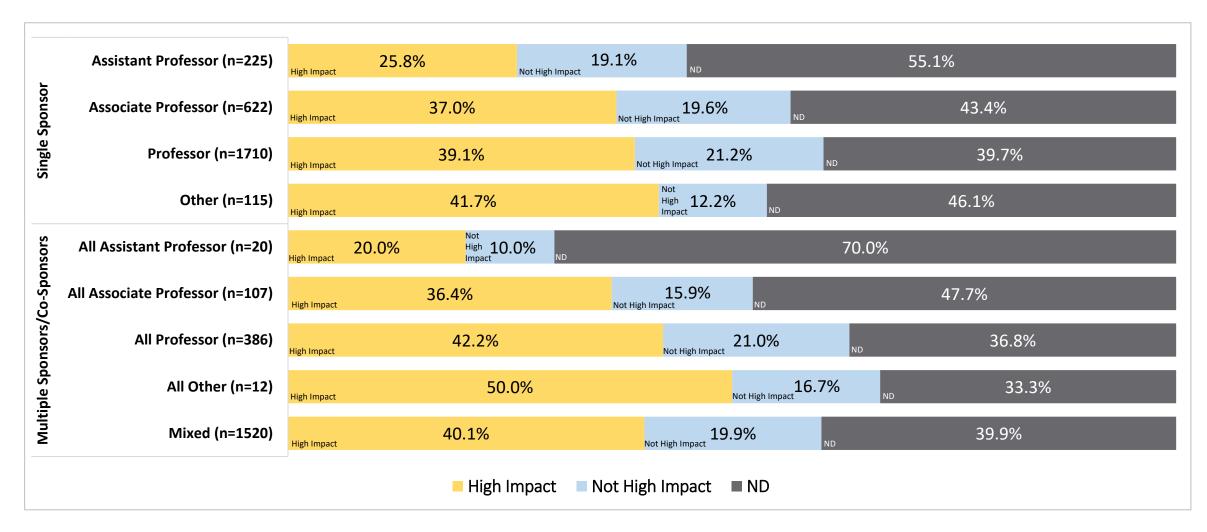


Applications from schools that submit more applications have better review outcomes

NRSA review outcomes according to the number of applications the applicant organization submitted in 2021



Review outcomes improve as the academic rank of the sponsor rises





Fellowship Review: 5 Criteria \rightarrow 3 Criteria

Achieved through similar process of extensive community input/engagement

Current

Overall Impact Score based on 5 criteria

- Fellowship Candidate
- Sponsors, Collaborators, Consultants
- Research Training Plan
- Training Potential
- Institutional Environment & Commitment to Training

Applications submitted on or after Jan 25, 2025

Overall Impact Score based on 3 criteria

- Candidate Preparedness and Potential
 - Wider range of indicators of scientific potential and preparedness
- Research Training Plan

Commitment to Candidate

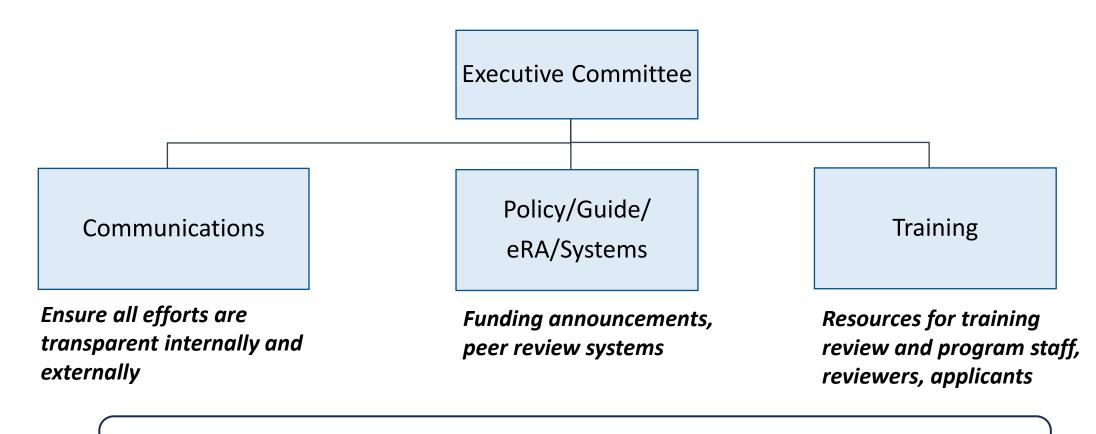
Evaluations of the sponsor and environment framed in terms of their contributions to the applicant's scientific training. Sponsor's extramural funding is not considered by peer reviewers.

Revised fellowship application

- Aligned with the new criteria for more emphasis on quality of the training plan; grades not required or allowed
- Shorter, more structured, targeted, reduces boilerplate language



Trans-NIH implementation committees for both RPG and F changes with deep, multidimensional domain expertise in peer review, communications, policy, eRA systems, reviewer training, staff training



Major launch of training for reviewers, chairs – Spring 2025



Learn more on NIH's one-stop shop sites for RPGs, Fellowships

Register for public webinars, view recorded webinars, resources, FAQs, and more

Research Project Grants (RPGs)

https://grants.nih.gov/policy/peer/simplifying-review.htm



Questions? <a>Simplifiedreview@nih.gov

Center for Scientific Review

Fellowships

https://grants.nih.gov/policy/peer/revisions-nihfellowship-application-review-process.htm

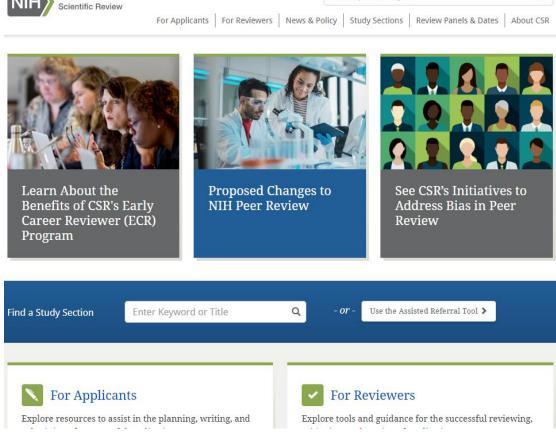
Register for the Sept 19 webinar



Questions? FellowshipReview@mail.nih.gov

Learn more about other CSR initiatives and priorities

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What are you searching for?

CSR's Website: https://public.csr.nih.gov/

- CSR's 2022-2027 Strategic Plan
- Data, full reports, analyses, e.g.
 - Upcoming changes in the review of RPGs, fellowships
 - Actions to address bias in peer review
 - Early Career Reviewer (ECR) program
 - In-person versus Zoom meeting evaluation
 - Reviewer demographics
 - CSR Advisory Council, Council working group reports
 And much more.....

Q/A, Discussion, Comments noni.byrnes@nih.gov



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