



Center for
Scientific Review

Strengthening NIH Peer Review – Changes to review of Research Project Grants and Fellowships

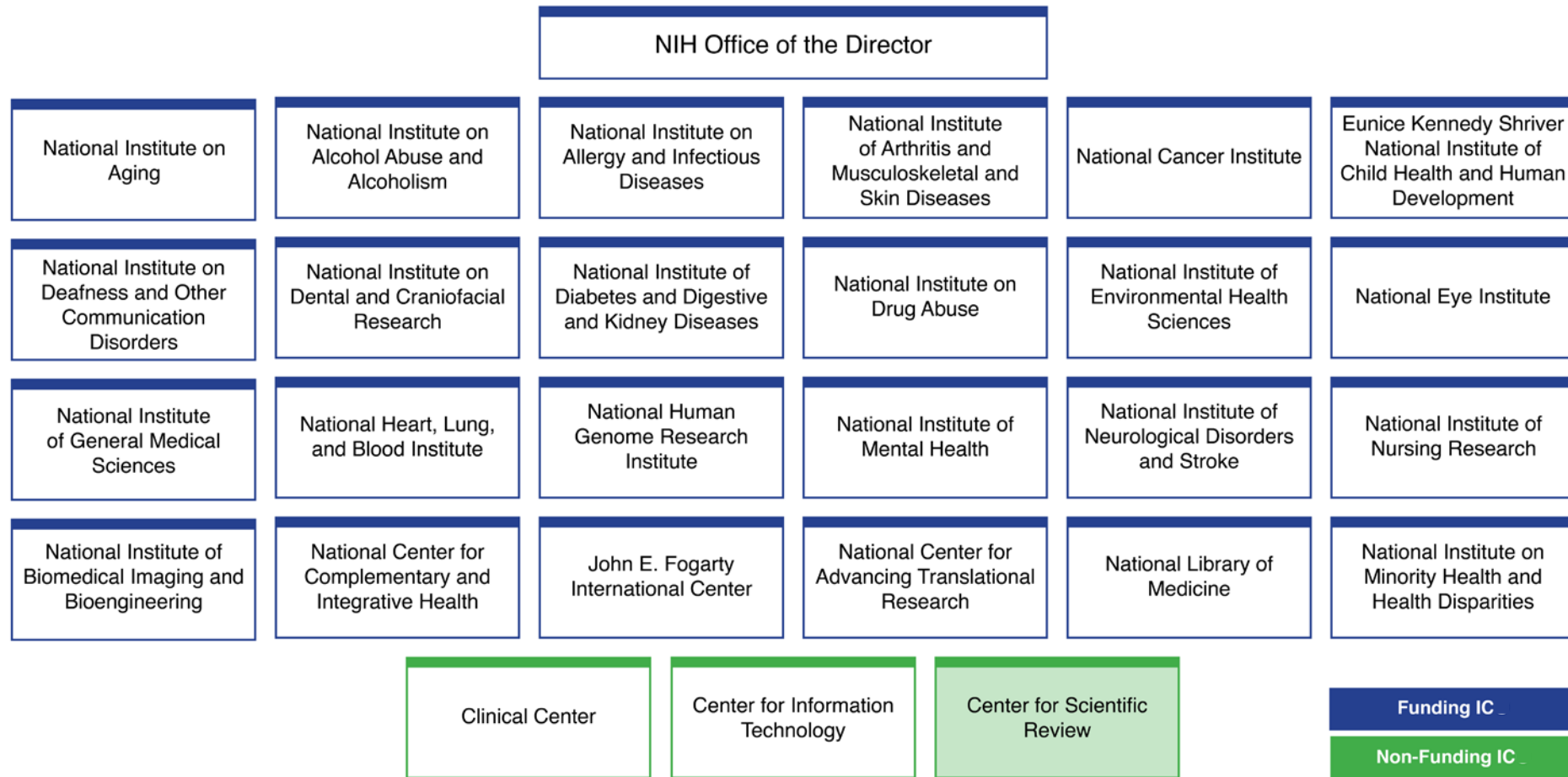
Valerie L. Durrant, Ph.D., Director

Division of AIDS, Behavior, and Population
Sciences Center for Scientific Review

National Institutes of Health



National Institutes of Health – 27 Institutes/Centers (ICs)

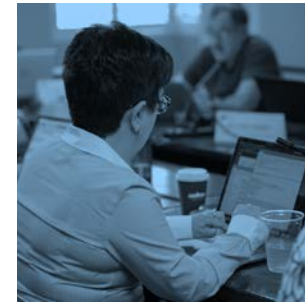
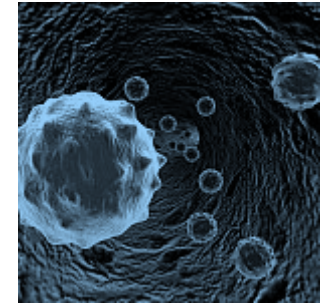


CSR manages a majority of peer review for all NIH funding ICs as well as the Office of the Director

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's Scope [Fiscal Year 2023]


~79,000
NIH Applications




~60,000 (76%)
Reviewed by CSR



94%
of NIH R01s



96%
of NIH SBIRs-STTRs



84%
of NIH NRSA Fellowships

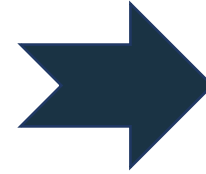
~19,000 reviewers, ~1,200 meetings

Simplifying Review Framework for NIH Research Project Grants

Motivation for Examining Application Review

1. Organization of peer review criteria had become too complex

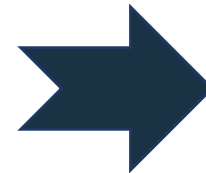
- Persistent feedback from reviewers and observed by NIH Staff
- Expansion of administrative and policy-compliance expectations for reviewers



Detracts attention away from the critical, primary role of reviewers to evaluate scientific merit

2. Undue influence of reputation in NIH peer review

- Concerns from the community
- Observations by NIH staff or NIH leadership



Affects judgements of merit when well known places/people are given a pass and others treated with more scrutiny

What Will Change Under the Simplified Review Framework for Research Project Grants?

1. Existing five review criteria reorganized into three factors
2. Investigator/Environment will be evaluated as sufficient or gaps identified (considered in overall impact score, but no individual score)
3. Some Additional Review Criteria (inclusions, study timeline) related to human subjects to be evaluated within Factor 2, for more rigorous review
4. Most Additional Review Considerations shifted from reviewers to NIH staff

Support the identification of the strongest, highest-impact research

The Simplified Review Framework Updates the Main Review Factors and Additional Criteria

MAIN REVIEW FACTORS – all affect Overall Impact score

- **Factor 1: Importance of the Research [scored]** - strengths/weaknesses
Significance, Innovation
 - **Factor 2: Rigor and Feasibility [scored]** - strengths/weaknesses
Approach
 - **Factor 3: Expertise and Resources [not scored]** - drop down- appropriate, or identify gaps
Investigators, Environment
- Study Timeline (for CT only)
 - Inclusion plans – sex/gender, race/ethnicity, based on age (HS and CT)

ADDITIONAL CRITERIA – not scored, but can affect Overall Impact score

- ~~• Study Timeline (for CT only)~~
- Human Subject Protections (for HS and CT)
- ~~• Inclusion of Women, Minorities, and Children (for HS and CT)~~
- Vertebrate Animal Protections
- Biohazards
- Resubmission/Renewal/Revisions

*Most “Additional Review Considerations”, which had no bearing on Overall Impact Score, **removed** from first-level peer review.*

Reviewers briefly comment on Budget and Chem/Bio resources authentication plans

Simplifying Review of Research Project Grant Applications: Mechanisms and Timeline

- **What applications are affected?**

- RPGs with the following activity codes:

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, (including the following phased awards: R21/R33, UH2/UH3, UG3/UH3, R61/R33)

- **When will the Simplified Framework be Implemented?**

- Applies to applications submitted for **January 25, 2025 due dates**
 - Summer 2025 peer review and October 2025 Advisory Council

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

Next Steps: Between Now and January 2025

Over the next year:

- Multiple public webinars
- Re-issuance of Notices of Funding Opportunity with changes to Section V (Application Review Information)
- Changes to NIH systems
- Developing training resources



One-stop shop, central NIH site with information, FAQs

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

Training/outreach to socialize the change for reviewers, chairs, applicants, staff

Community Input, Process and Timeline

Jan 2020 – April 2021:

- **Initial input gathering through blog posts** (Open Mike, Review Matters), strong response (>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 recommendations, publication of working group report

July 2021 – Sept 2022:

- Internal NIH input/modifications to the framework, **approval by IC and NIH leadership**

Dec 2022 – March 2023:

- **Public input** through NIH Request for Information (RFI) – majority supportive of changes [[RFI report](#)]

Learn More & Stay Informed

- Development background
- Description of changes
- Guidance for reviewers
- Guidance for applicants
- Training and resources
- Notices and reports
- FAQs
- Contacts

| COMPLIANCE |
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| Related List of Reviewer Documents |

VIEW

NEW DRAFT

Simplifying Review of Research P

NIH is implementing a simplified framework for the peer review of submissions with due dates of January 25, 2025. The changes are c

1. Enable peer reviewers to better focus on answering the key projects:
 - Should the proposed research project be conducted?
 - Can the proposed research project be conducted?
2. Reduce the potential for the review to be influenced by the



Background

Learn more about the N



Simplified Peer

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

Improving The Review of Fellowship (F) Applications

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



Ruth L. Kirschstein

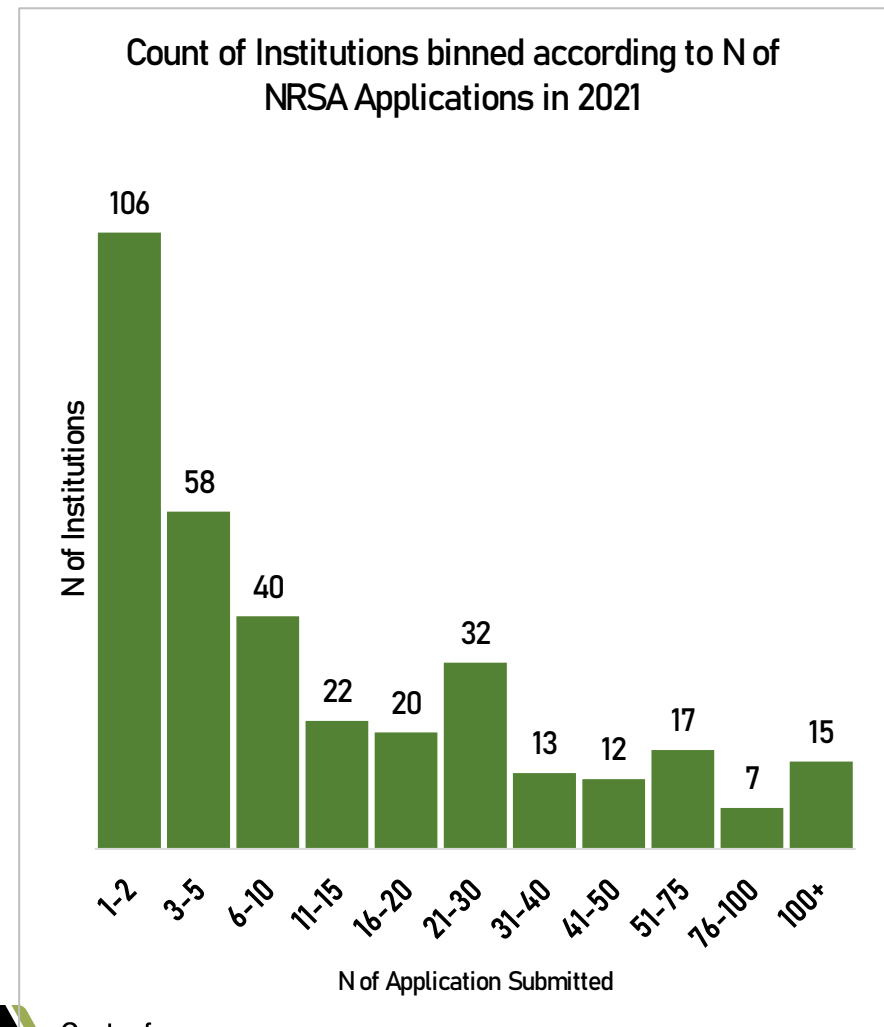
National Research Service Awards



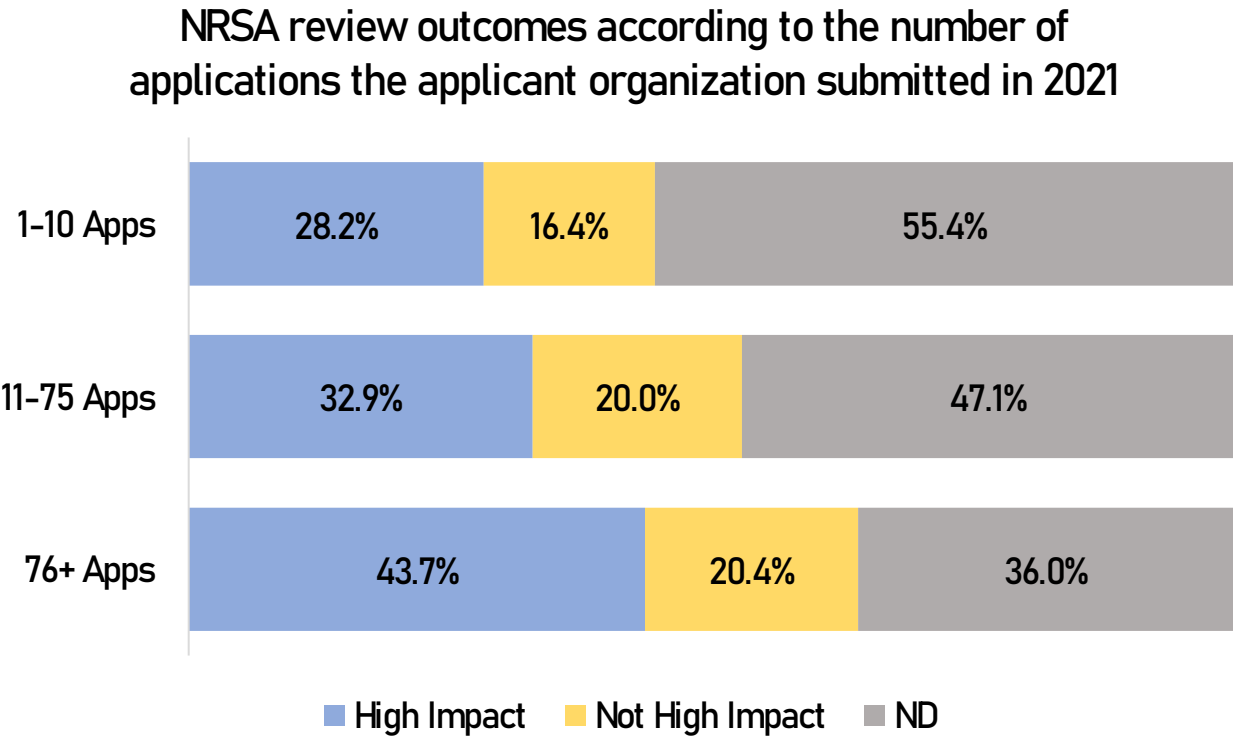
National Institutes of Health
Research Training and Career Development

- **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
- **Data analysis of >6,000 applications supported those concerns**
 - Fellowship applications are concentrated in a small number of institutions
 - Applications from those submitting a large number do better in review
 - Review outcomes for fellowships improve as the rank of the sponsor increases

Submissions are highly concentrated in a few institutions



Applications from schools that submit more applications do better review in review



Objectives of the changes

1. **Better focus reviewer attention on three key assessments:** the fellowship candidate's preparedness and potential, research training plan, and commitment to the candidate.
2. **Ensure that a broad range of candidates and research training contexts** can be recognized as meritorious by clarifying and simplifying the language in the application and review criteria.
3. **Reduce bias in review** by emphasizing the commitment to the candidate, without undue consideration of sponsor and institutional reputation.

Reorganized Fellowship Review Criteria Areas

Current Fellowship Review Headings



Fellowship Candidate



Sponsors, Collaborators,
Consultants



Research Training Plan



Training Potential



Institutional Environment &
Commitment to Training



New Fellowship Review Headings

1

Candidate Preparedness and Potential

2

Research Training Plan

3

Commitment to Candidate

No changes to *Additional Review Criteria* or to *Additional Review Considerations*

Changes to the fellowship application

1. **Eliminate grades** (request courses completed)
2. **Revise the Applicant Section**
 - Better assess the candidate's scientific thinking
 - Broaden consideration of qualifications
3. **Revise the Sponsors, Collaborators and Consultants section**
 - Emphasis on sponsor's mentorship approach, plan for this trainee and fit to trainee's goals and needs
4. **Revise letters of reference**
 - Targeted, trainee-specific questions in word-limited fields
 - Intended to discourage boilerplate and to make it easier for reviewers to evaluate
5. **No significant changes to the Research Training Project Plan Section**
 - Specific Aims, Research Strategy, Responsible Conduct of Research - unchanged
6. **An optional statement of special circumstances**
 - Situations that might have hindered their progress such as harassment, the COVID-19 pandemic, or other personal or professional circumstances

Revised instructions clearly indicate who is responsible for each part of the application.

When will the new framework be implemented?

Applications submitted for due dates on or after January 25, 2025

- April 8, 2025 application receipt date
- Summer 2025 peer review
- October 2025 Advisory Council

Scope?

All NRSA activities (F30, F31, F32, F33, F99, K00)

More information: <https://grants.nih.gov/policy/peer/revisions-nih-fellowship-application-review-process.htm>

Simplifying Review Implementation Timeline for RPGs and Fs



*Applications with a due date on or after **January 25, 2025**

RPGs: New review framework

Fs: New application form
New review framework

Questions?