

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

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

		NIH Office of the Director			
National Institute on Aging	National Institute on Alcohol Abuse and Alcoholism	National Institute on Allergy and Infectious Diseases	National Institute of Arthritis and Musculoskeletal and Skin Diseases	National Cancer Institute	Eunice Kennedy Shriver National Institute of Child Health and Human Development
National Institute on Deafness and Other Communication Disorders	National Institute on Dental and Craniofacial Research	National Institute of Diabetes and Digestive and Kidney Diseases	National Institute on Drug Abuse	National Institute of Environmental Health Sciences	National Eye Institute
National Institute of General Medical Sciences	National Heart, Lung, and Blood Institute	National Human Genome Research Institute	National Institute of Mental Health	National Institute of Neurological Disorders and Stroke	National Institute of Nursing Research
National Institute of Biomedical Imaging and Bioengineering	National Center for Complementary and Integrative Health	John E. Fogarty International Center	National Center for Advancing Translational Research	National Library of Medicine	National Institute on Minority Health and Health Disparities
	Clinical Center Center for Information Center		Information Center for	r Scientific	Funding IC
	Cinical	Tech	nology Rev	view	Non-Funding IC

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



### **CSR's Mission**







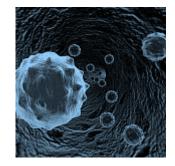






To ensure that NIH grant applications receive fair, independent, expert, and timely scientific reviews - free from inappropriate influences - so NIH can fund the most promising research.















## CSR's Scope [Fiscal Year 2023]



#### ~19,000 reviewers, ~1,200 meetings



## Simplifying Review Framework for NIH Research Project Grants



# 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



### **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 policycompliance expectations for reviewers

# 2. Undue influence of reputation in NIH peer review

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



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



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



#### 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

#### 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



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- Study Timeline (for CT only)
- Inclusion plans sex/gender,
   race/ethnicity, based on age (HS and CT)

Most "Additional Review <u>Considerations</u>", 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 (RPG) 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: <a href="mailto:grants.nih.gov/policy/peer/simplifying-review.htm">grants.nih.gov/policy/peer/simplifying-review.htm</a>



#### 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

	RANTS & FUNDING entral Resource for Grants and Funding Information	eRA   NIH Staff 🖀   Glossary   <u>FAQs</u>   Help
HOME ABOUT	GRANTS FUNDING POLICY & COMPLIAN	CE NEWS & EVENTS ABOUT OER
ome » Policy & Complia	nce » Peer Review Policies and Practices » Simplifying Revi	iew of Research Project Grant
COMPLIANCE Policy Topics	Simplifying Review of Resear Applications	-
Peer Review Policies and Practices	of the majority of competing research project grant (RPG) applications, beginning with submissions with due dates	
Simplifying Review of Research Project Grant Applications	January 25, 2025. The changes are designed to: 1. Enable peer reviewers to better focus on answering the key questions necessary to assess the scientific and	nd
Background	technical merit of proposed research projects:	Learn more
Simplified Peer Review Framework	<ul> <li>Should the proposed research project be conducted?</li> </ul>	

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

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



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

VIEW

## Learn More & Stay Informed

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

eview Policies and Practices
mplifying Review of Research Project Grant pplications
Background
Simplified Peer Review Framework
Reviewer Guidance
Applicant Guidance
FAQ
Training and Resources
Notices
Contacts
Recommendations for Improving NRSA Fellowship Review
Proposed Reviewer Guidance and Application nstructions
ar aging Conflict of Interest

dated List of Reviewer Documents

opics

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 of

- Enable peer reviewers to better focus on answering the key projects:
  - Should the proposed research project be conducted

NEW DRAFT

• Can the proposed research project be conducted?

2. Reduce the potential for the review to be influenced by the

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#### Background

Learn more about the N

Simplified Peer

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



## Improving The Review of Fellowship (F) Applications



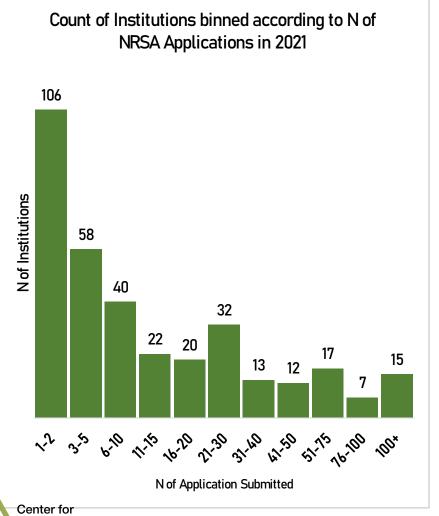
Goal: Optimize the identification and training of the most promising scientists of the next generation



- 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

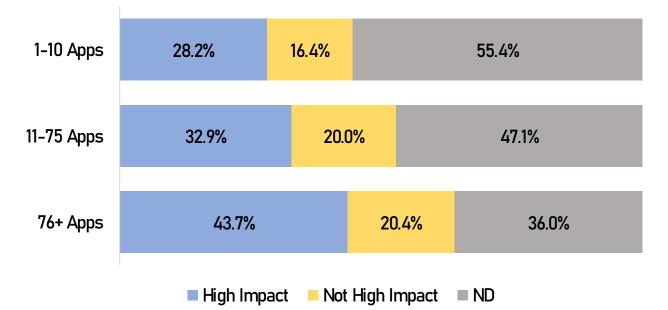


# Submissions are highly concentrated in a few institutions



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

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





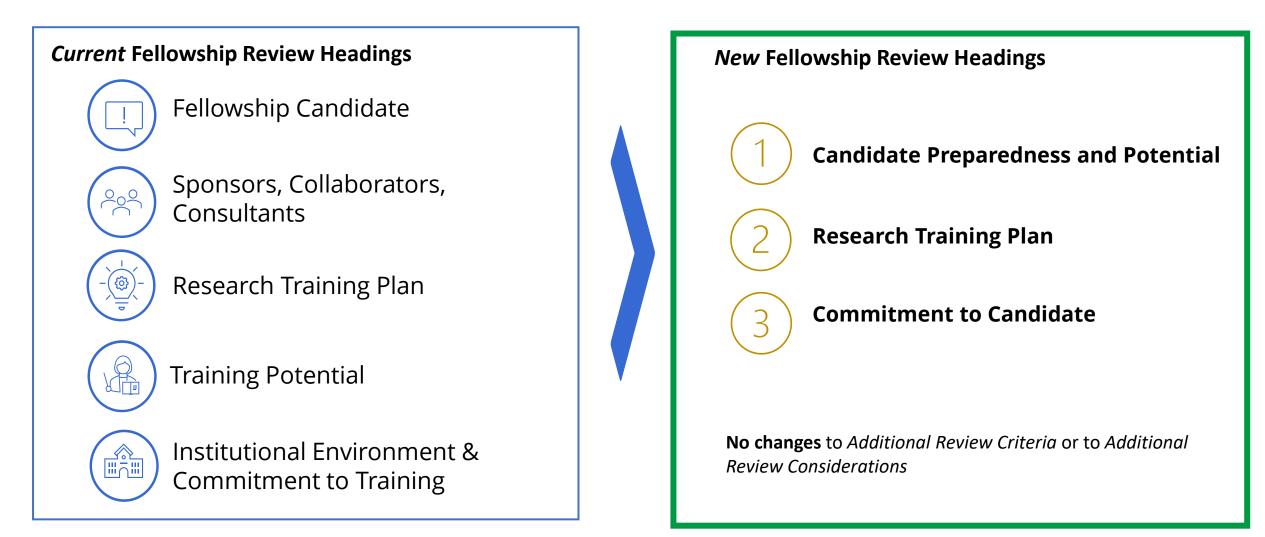
## **Objectives of the changes**

#### **1.** Better focus reviewer attention on three key assessments:

- Fellowship candidate's preparedness and potential
- Research training plan
- 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**





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## **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: <u>https://grants.nih.gov/policy/peer/revisions-nih-fellowship-application-review-process.htm</u>



#### Overview of Grant Application and Review Changes for Due Dates On or After January 25, 2025

✓ Simplified Review Framework for Most Research Project Grants

✓ Improvements to the NRSA Fellowship Application and Review Process

- Updates to Reference Letter Guidance
  - Will apply to reference letters for fellowship (F) and mentored career development (K) awards.
- Updates to NRSA Institutional Training Grant Applications
  - Changes to tables and forms
  - Webinar on June 5: Updates to NIH Training Grant Applications (registration open)
- Updated Application Forms (FORMS-I)
  - Available Fall 2024
- Common Forms for Biographical Sketch and Current and Pending (Other) Support
  - Greater standardization across federal agencies
  - Provide clarity regarding disclosure requirements and processes



### **Centralized Web Page**

Grants.nih.gov/policy/changes-coming-

#### jan-2025

Will be continually updated with notices • and resources



#### **GRANTS & FUNDING**

NIH Central Resource for Grants and Funding Information

#### Changes Coming to NIH Applications and Peer Review in 2025

This page serves as a central location where you can learn more about multiple changes coming in 2025 that will affect the submission and review of NIH

These changes include updates to the peer review and submission of most research project grants, fellowships, and training grants; Common Forms for and Current and Pending (Other) Support; updated instructions for reference letters; and the transition to FORMS-I application instructions. The changes support for a broader range of investigators by simplifying, clarifying, and ensuring greater fairness in the peer review process by reducing the undue effe The hope is that these changes will level the playing field so that no applicant has an unfair advantage over another.

#### Upcoming Webinars

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Below is a list of upcoming webinars on changes coming in 2025.

- April 17, 2024: NIH Simplified Review Framework for Research Project Grants (RPGs): Implementation and Impact on Funding Opportunities
- June 5, 2024: Webinar on changes to NIH NRSA training grant applications (registration coming soon)
- September 19, 2024: Webinar on changes to NIH NRSA fellowship application and review (registration coming summer 2024)

#### Simplified Review Framework for Most Research Project Grants (RPGs)

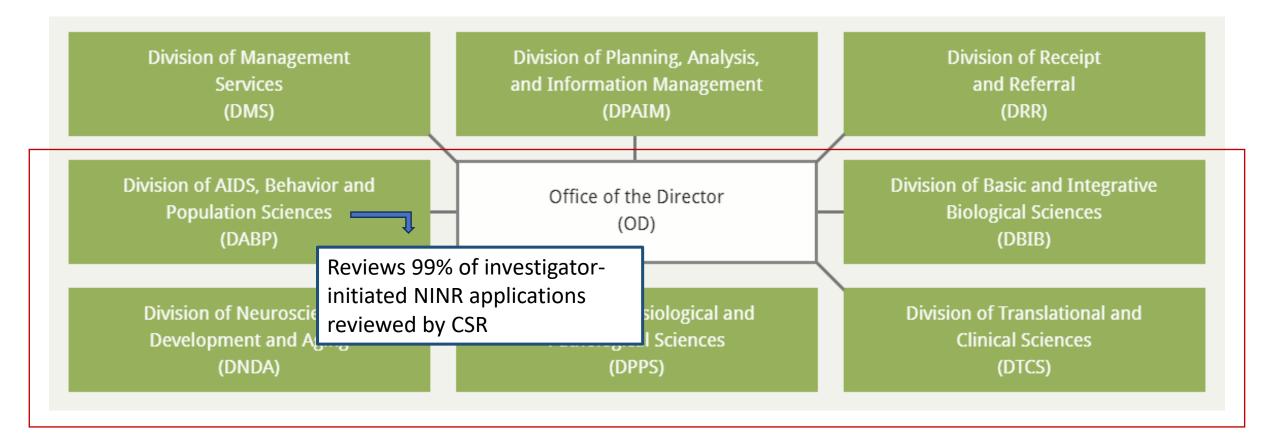
NIH is implementing a simplified framework for the peer review of the majority of competing RPG applications. This change is designed to reduce bias in peer review while enabling reviewers to better focus on answering the key questions necessary to assess the scientific and technical merit of proposed research projects: Can and should the proposed research project be conducted?

#### Improvements to the NIH Fellowship Application and **Review Process**

NIH is revising the fellowship review criteria used to evaluate NRSA fellowship applications



## **CSR Organizational Chart**



https://public.csr.nih.gov/AboutCSR/Organization/Chart



https://public.csr.nih.gov/StudySections/ReviewBranches

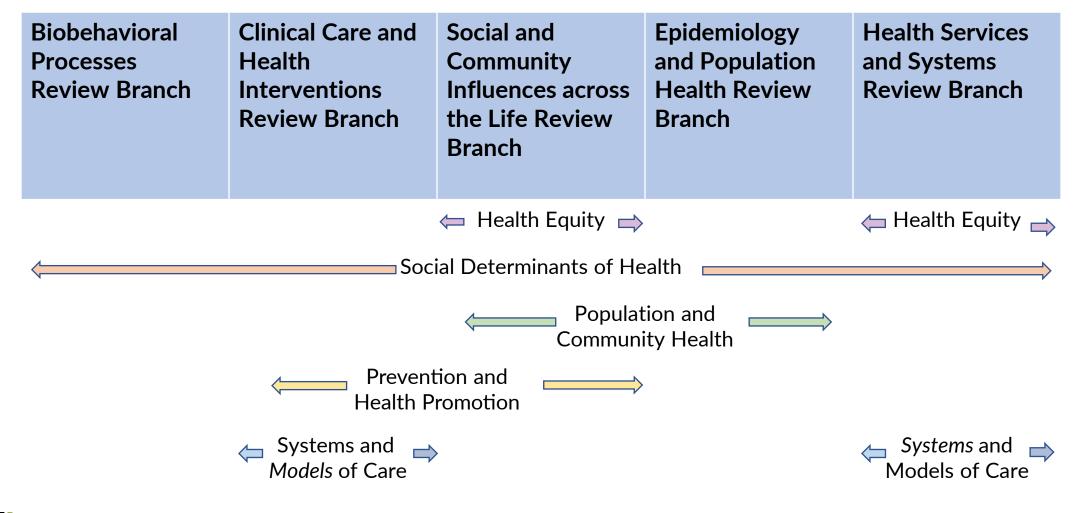
## How NINR strategic plan maps to CSR DABP branches\*

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\*Where applications are likely to be concentrated. Individual assignments will vary.

## How NINR strategic plan maps to CSR DABP branches\*



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\*Where applications are likely to be concentrated. Individual assignments will vary.

### **Distribution of NINR applications assigned to CSR DABP branches**\*

Biobehavioral Processes Review Branch	Clinical Care and Health Interventions Review Branch	Social and Community Influences across Life Rev Branch	Epidemiology and Population Health Review Branch	Health Services and Systems Review Branch
(3%)	(46%)	(20%)	(2%)	(28%)



\*FY 2023, excludes applications received in response to RFAs

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(3%)	(46%)	(20%)	(2%)	(28%)	
28%	Clinical care in General Care (CMGC) Specialty Care Settings (ICSC)	Community oriented study sections (CIHB and HPC) 11%		Health services (ODHS HSQE HHD)	15%
9% –	Biobehavioral Medicine & Health Outcomes (BMHO)				



\*FY 2023, excludes applications received in response to RFAs

## **Questions?**



### **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]

