U.S. Department of Health & Human Services

NIH Center for Scientific Review

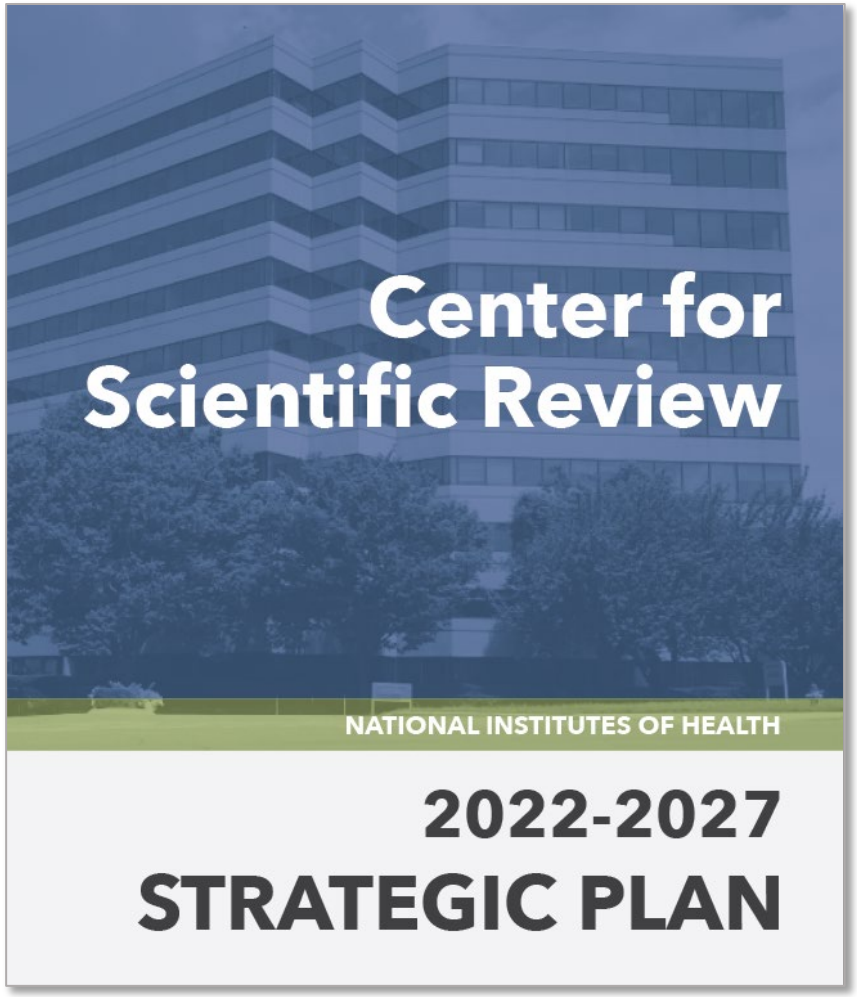
Proposed New Framework for NIH Peer Review Criteria

Noni Byrnes, PhD
Director
Center for Scientific Review

Advisory Committee to the Director, NIH
December 8, 2022

Background

- CSR oversees the review of ~61,000 (76%) NIH applications each year, including ~94% of Research Project Grants (RPGs) and ~85% of NRSA Fellowship (F) applications
- CSR is committed to ***"implement changes to the peer review process to make it more fair, effective, and efficient"*** – one of five overarching goals in CSR's Strategic Plan
- Proposed changes to RPG and F review frameworks based on recommendations of CSR Advisory Council working groups and input from NIH and IC leadership



Proposed Changes to RPG Peer Review

Two main goals

- **Refocus first-level peer review on its singular role of providing advice to the agency regarding the scientific/technical merit of grant applications**, *relieving reviewers of responsibility for administrative/policy compliance items, reducing burden and incentivizing participation in review.*

- **Mitigate reputational bias in the peer review process** – *specifically, refocusing the evaluation of investigator and environment to in the context of the proposed research project*

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

CSR Advisory Council Working Groups on Simplifying Review Criteria [Non-Clinical Trials & Clinical Trials]

CSR Advisory Council

Jinming Gao, Ph.D. (non-CT)
Elaine Dewey Sammons Distinguished Chair in Cancer Research
Professor of Oncology, Pharmacology, Otolaryngology, and Cell Biology
UT Southwestern Medical Center

Alfred George, M.D. (Both)
Magerstadt Chair and Alfred Newton Richards Professor of Pharmacology
Director, Center for Pharmacogenomics
Northwestern School of Medicine

Yasmin Hurd, Ph.D. (Both)
Professor, Ward-Coleman Chair of Translational Neuroscience
Director of the Addiction Institute
Icahn School of Medicine, Mt. Sinai

Deanna Kroetz, Ph.D. (non-CT)
Jere E. Goyan Presidential Chair, Department of Bioengineering and Therapeutic Sciences
UCSF School of Pharmacy

José López, M.D. (non-CT)
Professor, Division of Hematology, University of Washington
Member, Bloodworks Northwest Research Institute

Tonya Palermo, Ph.D. (Co-Chair) (Both)
Professor, Anesthesiology and Pain Medicine
Associate Director of the Center for Child Health, Behavior and Development
Seattle Children's Research Institute

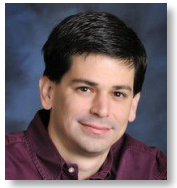
Ad-hoc

Brian Boyd, Ph.D. (CT)
William C. Friday Distinguished Professor in Education
University of North Carolina at Chapel Hill

Matthew Carpenter, Ph.D. (CT)
Professor, Depts. of Psychiatry & Behavioral Sciences, and Public Health Sciences,
Co-Director, Tobacco Research and Cancer Control Programs, Hollings Cancer Center
Medical University of South Carolina

Kevin Corbett, Ph.D. (non-CT)
Associate Professor of Cellular and Molecular Medicine
UC San Diego

Michelle Janelsins, Ph.D. (Both)
Associate Professor of Surgery
Member, Prevention and Control Program, Wilmot Cancer Institute
University of Rochester School of Medicine



Brooks King-Casas, Ph.D. (Both)
Associate Professor, Department of Psychiatry and Behavioral Medicine
Fralin Biomedical Research Institute
Virginia Tech School of Medicine

Pamela Munster, M.D. (CT)
Professor, Department of Medicine, Hematology/Oncology,
Director, Early Phase Clinical Trials Unit
UCSF Helen Diller Family Comprehensive Cancer Center

NIH Staff

Bruce Reed, Ph.D. (Co-Chair) (Both)
Deputy Director
NIH Center for Scientific Review

Sally Amero, Ph.D. (Both)
Review Policy Officer
NIH Office of Extramural Research

Process and Timeline

- **Scope**: RPGs, with a focus on R01s/R21s
- **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** - *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.*
- **January 2020 – April 2021:** Input gathering through blog posts (Open Mike, Review Matters), content analyses provided to working groups, 11 virtual meetings to develop framework and recommendations, CSR Advisory Council approval of recommendations, publication of working group report.
- **July 2021 – September 2022:** Internal NIH input/modifications, NIH and IC leadership approval of proposed framework
- **November 2022 –** NIH ACD presentation
- **December 2022** – RFI issued

Overview of proposed RPG review framework

Overall Impact Score – every application will continue to receive an Overall Impact score (no change)

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: Expertise & Resources** (Investigator, Environment) – *not scored, affects overall impact score*

Most "Additional Review **Criteria,** which affect Overall Impact Score (Human Subjects/Vertebrate Animals), remain unchanged

Most "Additional Review **Considerations,** which have no bearing on Overall Impact Score, removed from 1st level peer review

CURRENT

Main Review Criteria (affect Overall Impact Score)

PROPOSED

- Significance [scored] – strengths/weaknesses
- Investigator(s) [scored] - strengths/weaknesses
- Innovation [scored] - strengths/weaknesses
- Approach [scored] - strengths/weaknesses
- Environment [scored] - strengths/weaknesses

- **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 Review Criteria (concerns can affect Overall Impact Score)

- Human Subject Protections
- Inclusion of Women, Minorities, and Children
- Vertebrate Animal Protections
- Biohazards
- Resubmission/Renewal/Revisions

- Human Subject Protections
- Inclusion of Women, Minorities, and Across the Lifespan
- Vertebrate Animal Protections
- Biohazards
- Resubmission/Renewal/Revisions

Additional Review Considerations (no effect on Overall Impact Score)

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

- Authentication of Key Biological and/or Chemical Resources
- Budget and Period of Support

Proposed FACTOR 1. IMPORTANCE OF THE RESEARCH [scored]

Significance:

- Evaluate the importance of the proposed research in the context of current scientific challenges and opportunities, either for advancing knowledge within the field, or more broadly. Assess whether the application addresses an important gap in knowledge in the field, would solve a critical problem, or create a valuable conceptual or technical advance.
- Evaluate the rationale for undertaking the study, the rigor of the scientific background for the work (e.g. prior literature and/or preliminary data) and whether the scientific background justifies the proposed study.

Innovation:

- Assess the influence of scientific innovation on the importance of the proposed research. Note that while technical or conceptual innovation can influence the importance of undertaking the work, a project that is not applying novel concepts or approaches may be of critical importance for the field.
- Assess whether the proposed work applies novel concepts, methods or technologies in ways that will enhance the overall impact of the project.

Factor 1 would be scored 1-9, and reviewers would provide a narrative identifying major strengths & weaknesses.

Proposed FACTOR 2. RIGOR AND FEASIBILITY [scored]

Approach: Evaluate the scientific quality of the proposed work. Evaluate the likelihood that compelling, reproducible findings will result (rigor) and assess whether the proposed studies can be done well and within the timeframes proposed (feasibility).

Rigor:

- Evaluate the potential to produce unbiased, reproducible, robust data.
- Evaluate the rigor of experimental design and whether appropriate controls are in place.
- Evaluate whether the sample size is sufficient and well-justified.
- Assess the quality of the plans for analysis, interpretation, and reporting of results.
- Evaluate whether the investigators presented adequate plans to address relevant biological variables, such as sex or age, in the design, analysis, and reporting.
- For applications involving human subjects or vertebrate animals, also evaluate:
  - the rigor of the intervention or study manipulation (if applicable to the study design).
  - whether outcome variables are justified.
  - whether the results will be generalizable or, in the case of a rare disease/special group, relevant to the particular subgroup.
  - whether the sample will contain sufficient representative diversity to address the proposed question(s).

Feasibility:

- Evaluate whether the proposed approach is sound and achievable, including plans to address problems or new challenges that emerge in the work. For proposed studies in which feasibility may be less certain, evaluate whether the uncertainty is balanced by the potential for major advances.

Factor 2 would be scored 1-9, and reviewers would provide a narrative identifying major strengths & weaknesses.

Proposed FACTOR 3. EXPERTISE AND RESOURCES [not individually scored but affects Overall Impact Score]

Investigator(s): Evaluate whether the investigator(s) have the demonstrated background, training, and expertise, as appropriate for their career stage, to successfully conduct the proposed work. For Multiple Principal Investigator (MPI) applications, assess the quality of the leadership plan to facilitate coordination and collaboration.

[Drop down rating]

- Fully capable → no writeup needed.
- Identify need for additional expertise/capability and/or modification of leadership plan → briefly address specific gaps in expertise needed to carry out the project.

Environment: Evaluate whether the institutional resources are appropriate to ensure the successful execution of the proposed work.

[Drop down rating]

- Appropriate → no writeup needed.
- Identify need for additional resources → briefly address specific gaps in resources needed to carry out the project.

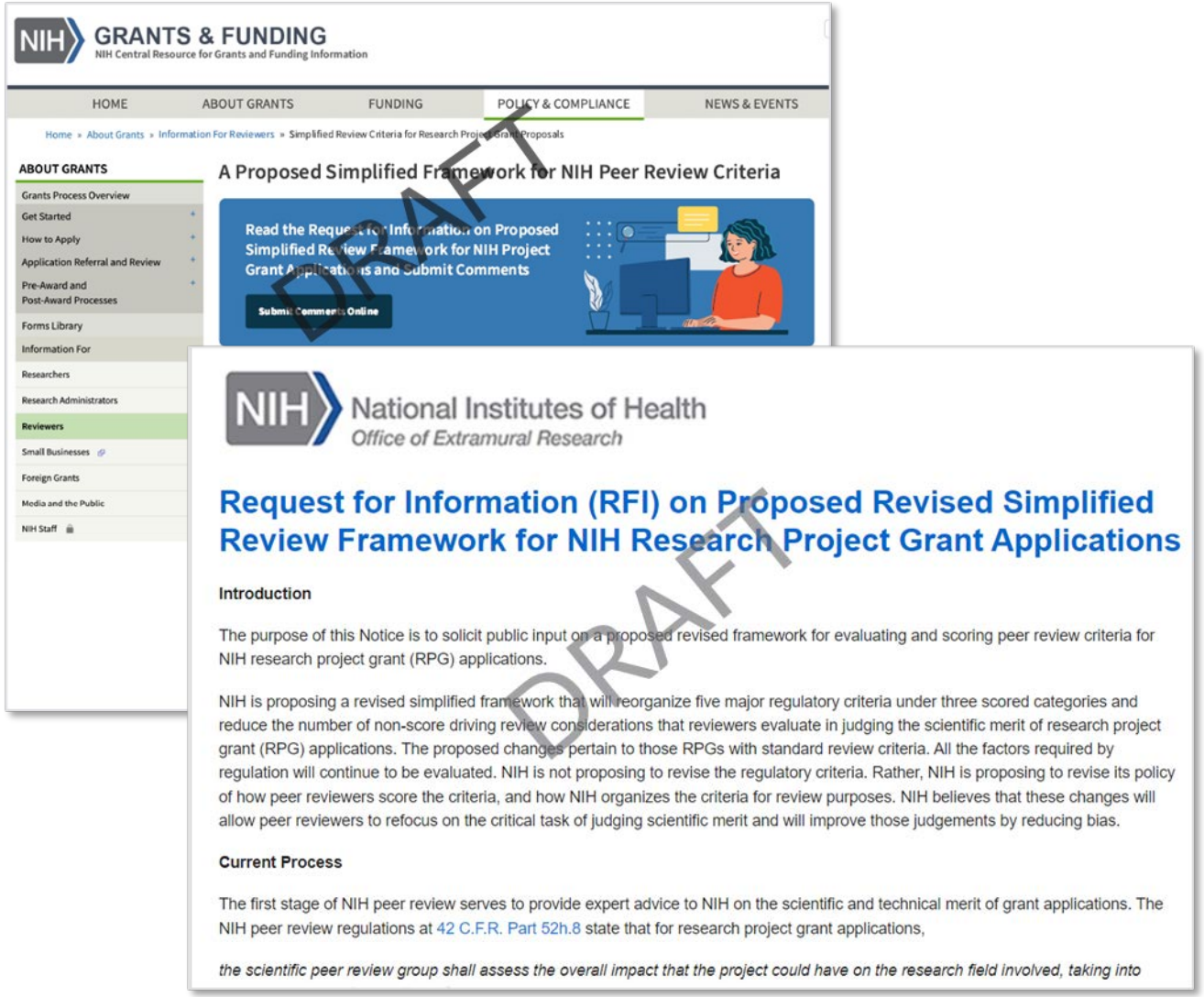
Factor 3 would not receive an individual score but would affect the Overall Impact Score. Reviewers would provide a narrative if they identified gaps in expertise/capability or resources.

Current Status

- Trans-NIH committee currently incorporating 1) rigorous CT RPG reviews and 2) (BRAIN Initiative's) Plan to Enhance Diverse Perspectives (PEDP) into proposed RPG review framework

- **RFI: Open until March 2023** – questions? simplifiedreview@nih.gov

- **More information:** https://grants.nih.gov/policy/peer/Proposed-Framework/index.htm



Proposed Changes to NRSA Fellowship Peer Review

Background and Charge

- Persistent concerns that NRSA fellowship reviews disadvantage some highly-qualified applicants
- In September 2021, CSR convened a working group of its advisory council
- Charge: Evaluate the NRSA fellowship review process and make recommendations to strengthen its fairness and effectiveness

Members of CSR Advisory Council

CSR Advisory Council

Chair

Elizabeth Villa, Ph.D.

University of California San Diego

Narasimhan Rajaram, Ph.D.

University of Arkansas at Fayetteville

Working Group Ad Hocs

Michael Burton, Ph.D.

University of Texas at Dallas

Robin Queen, Ph.D.

Virginia Tech

Katherine Friedman, Ph.D.

Vanderbilt University

Nathan Vanderford, Ph.D.

University of Kentucky

Barbara Kazmierczak, MD, Ph.D.

Yale University

Judith Yanowitz, Ph.D.

Magee-Women's Research Institute

Scott Miller, Ph.D.

Yale University

NIH Staff

Co-Chair

Bruce Reed, Ph.D.

Center for Scientific Review

Ericka Boone, Ph.D.

Division of Biomedical Research Workforce, Office of Extramural Research

Alison Gammie, Ph.D.

Division of Training, Workforce Development, and Diversity, National Institute of General Medical Sciences

Lystranne Maynard-Smith, Ph.D.

Center for Scientific Review

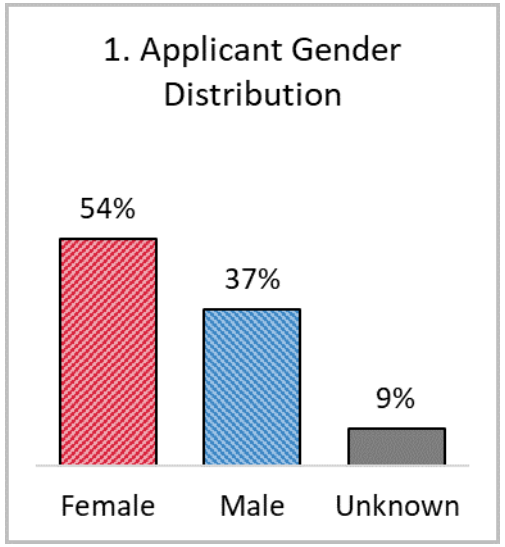
Cibu Thomas, Ph.D.

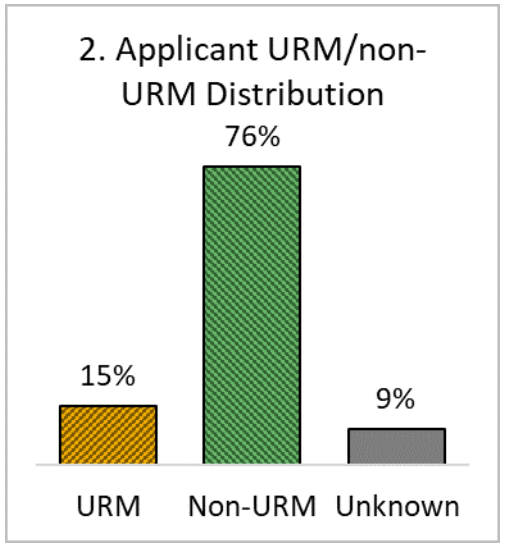
Center for Scientific Review

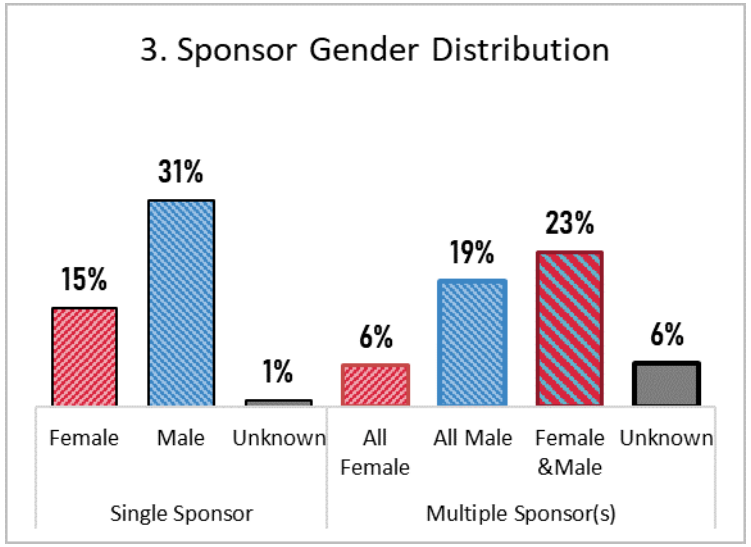
Process and Timeline

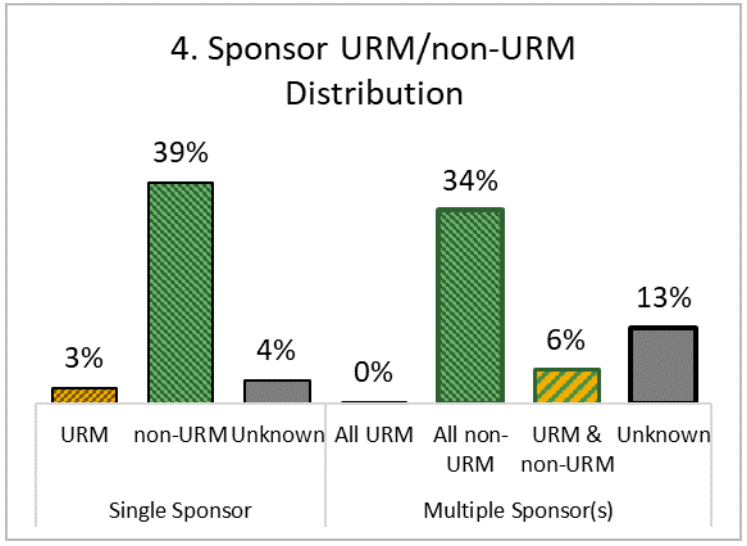
- **Scope**: NRSA fellowship applications (F30, F31, F32, F33)
- **September 2021 – August 2022:** Input gathering through blog posts (Open Mike, Review Matters), WG requested and provided with multiple data analyses on F applications/outcomes; content analyses provided to working groups, 12 virtual meetings to develop framework and recommendations
- **September 2022:** CSR Advisory Council approval of recommendations
- **October 2022:** Publication of working group report
- **December 2022:** ACD presentation
- **January/February 2023:** RFI to be issued

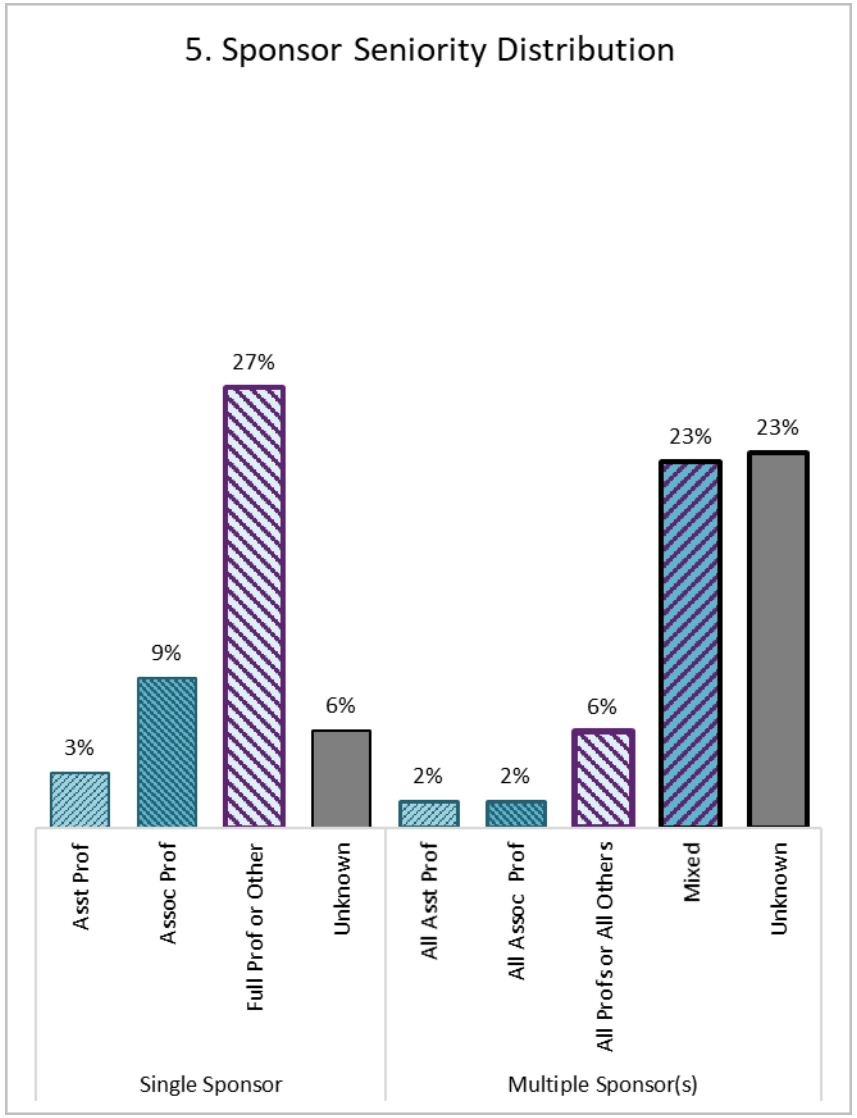
Data (career-stage and demographic): 2021 NRSA Fellowship Applications (#6676)



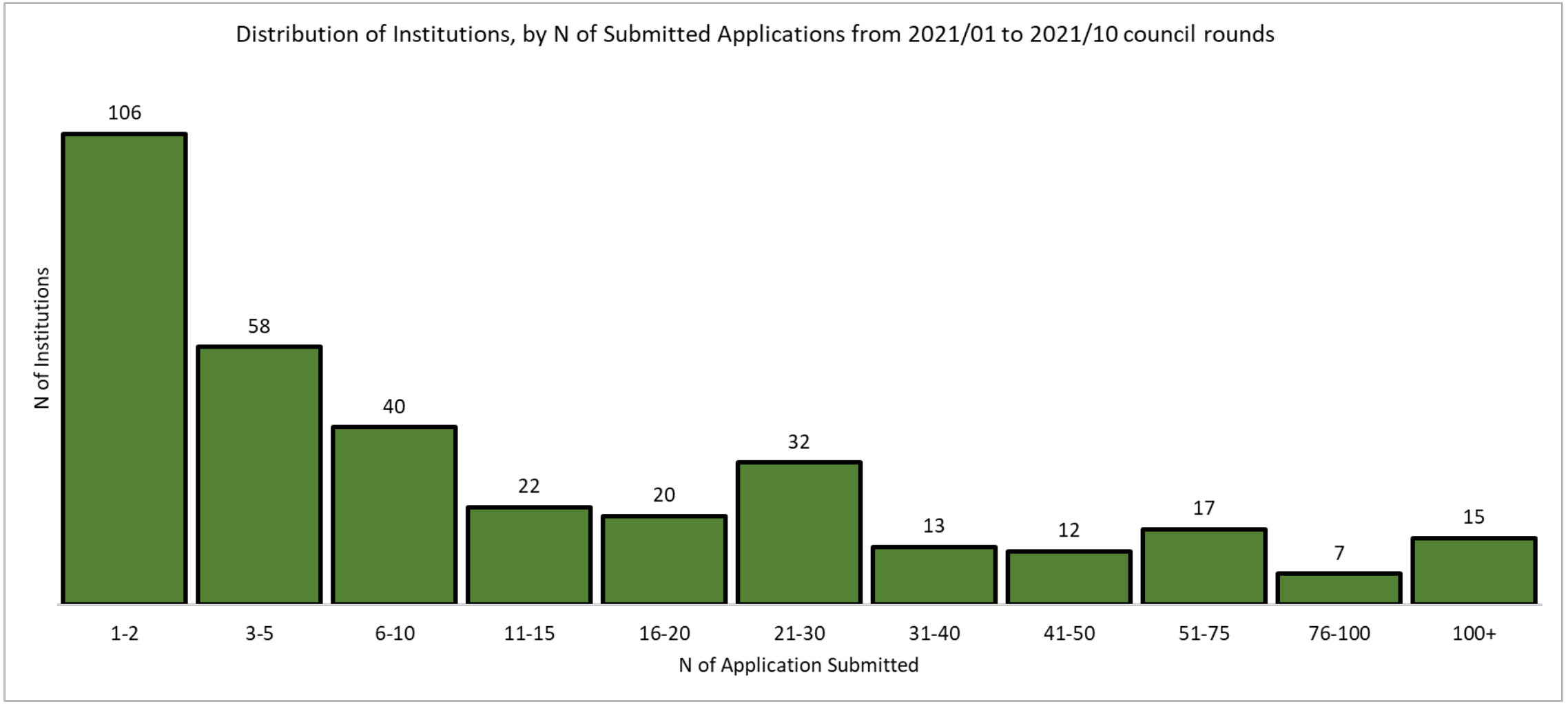




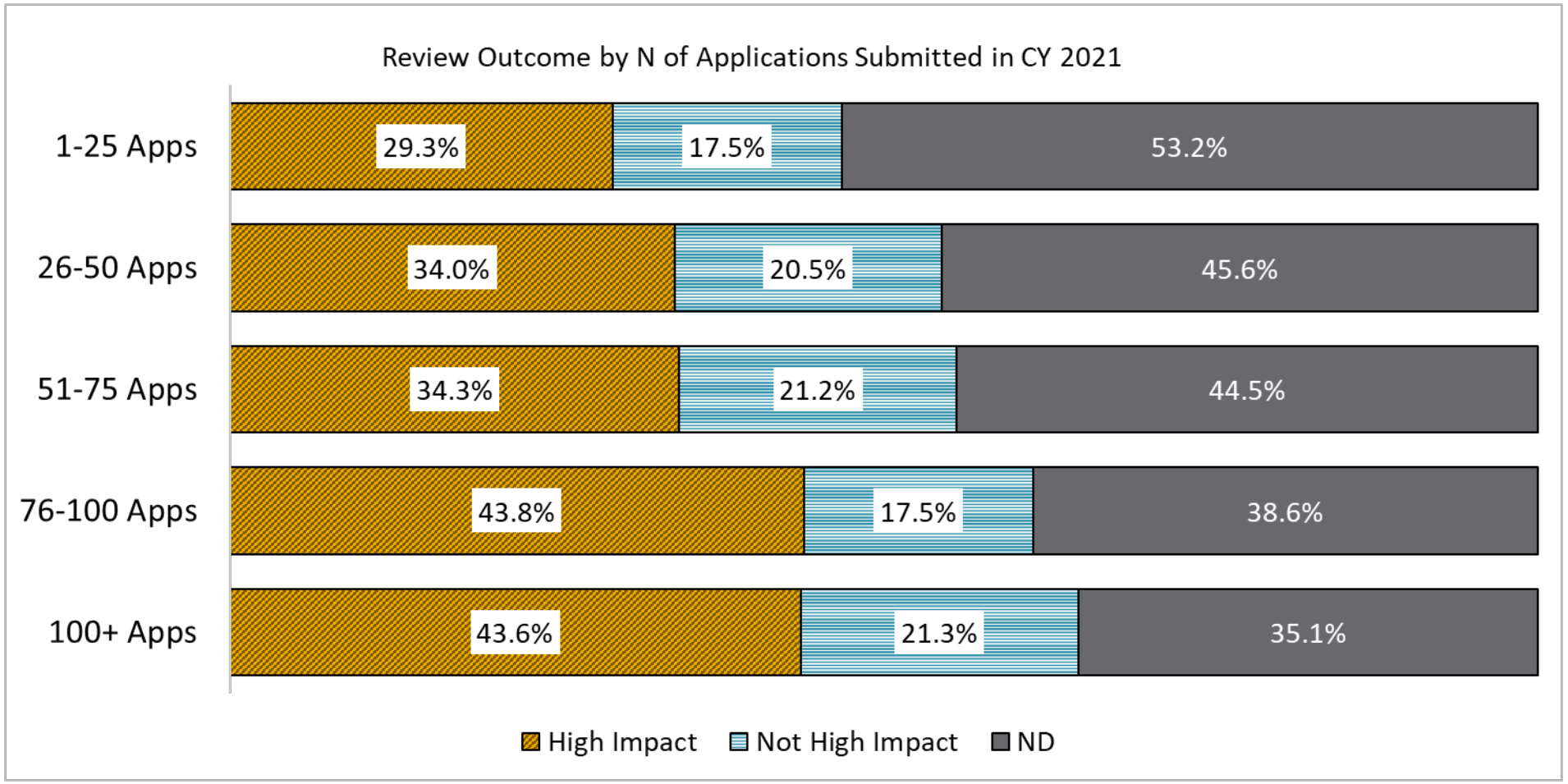




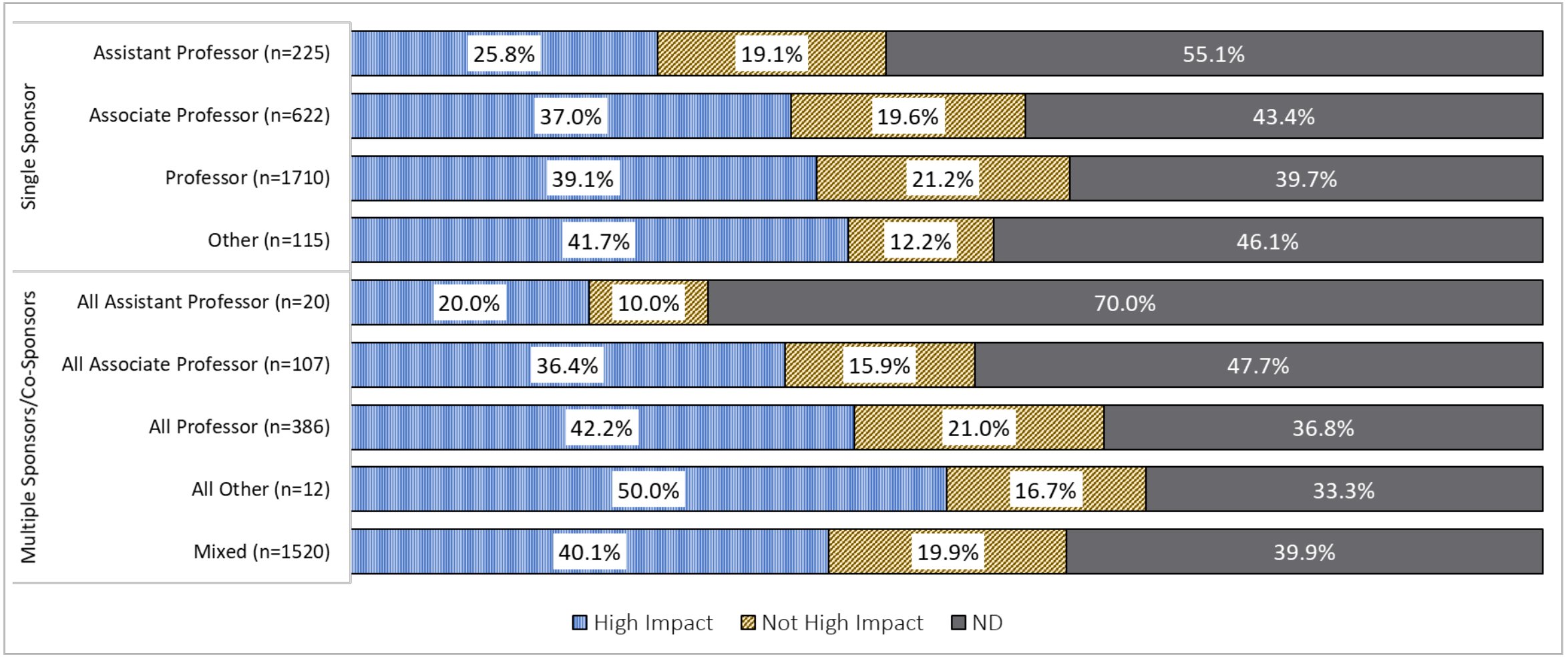
Applications are highly concentrated in a small number of institutions



Applications from institutions that submit low number of fellowship applications have worse review outcomes



Review outcomes improve as the academic rank of the sponsors rises



Summary

- The community feedback indicated concern that groups that are typically disadvantaged in science are disadvantaged in fellowship review. In addition, there are concerns about how applicant qualifications are defined, and concerns about the content of fellowship applications.

- Data shows that fellowship applications are concentrated in a small number of institutions, suggesting that the knowledge and other resources that support writing a good F application are very unevenly distributed.

- Applications from those (highly resourced) schools do better.

- Applications with senior scientists as sponsors do better than those with sponsors in earlier career stages.

- **NIH is potentially leaving out highly promising young scientists because of a process that too heavily favors elite institutions, senior, well-known sponsors, and an overly narrow emphasis on traditional markers of early academic success.**

Recommendations

Major recommendations:

1. Modify the review **criteria**
2. Modify the **information provided to reviewers,** i.e. fellowship application (Fellowship supplement to the PHS 424)

Additional recommendations:

1. Improve NIH outreach and reviewer training [targeted outreach; adapt CSR bias awareness training module for F reviews]
2. Consider changes to review process [clustering; partial-blinding]

Suggestions:

1. Consider granting honorable mentions to meritorious applicants who do not receive NRSA awards
2. Broaden the range of career goals that are welcomed by the NRSA program

Three main goals drove Recommendation 1: Modify the review criteria

1. Better focus reviewer attention on 3 key assessments (*become the 3 core criteria*):
   - Potential of the applicant
   - Strength of the science
   - Quality of the training plan

2. Define criteria to give less advantaged applicants a better chance—without disadvantaging others.
   - Evaluate accomplishments and trajectory in the context of their opportunities
   - In addition to accomplishments, evaluate personal characteristics that contribute to success

3. Reduce bias in review by reducing inappropriate consideration of sponsor and institutional reputation.
   - Evaluate sponsor and institution with respect to the quality of the science and quality of the training plan

Proposed revisions to fellowship review criteria

Current

1. Fellowship Applicant
2. Sponsors, Collaborators, & Consultants
3. Research Training Plan
4. Training Potential
5. Institutional Environment & Commitment to Training

Recommended

1. Scientific potential, fellowship goals, and preparedness of the applicant
2. Science and scientific resources
3. Training plan and training resources

Recommendation 2. Change the information provided to reviewers

1. **Eliminate undergraduate grades –** instead, include list of courses taken

2. **Revise the Fellowship Applicant section *to better align with review criteria; to allow applicants to present their scientific thinking, their needs, qualifications, and goals*** - 5 structured, character-limited statements (professional/fellowship goals, fellowship qualifications, self-assessment, scientific perspective, and a detailed account of activities planned under the award)

3. **No changes to the current Research Training Plan** (Specific Aims, Research strategy, respective contributions, RCR, etc.)

4. **Revise the Sponsors, Collaborators and Consultants section *to align with review criteria; place greater emphasis on sponsor's training/mentorship approach and plan for this particular student (not simply track record)*** -- structured, character-limited sections (training plan, environment, and research facilities; the number of fellows/trainees to be supervised during the fellowship; applicant's qualifications and potential for a research career)

5. **Revise letters of support *to address targeted, trainee-specific questions in structured fields to discourages boilerplate language, makes it easier for reviewers to differentiate and evaluate***

6. **Allow an *optional* statement of special circumstances** to address situations that might have hindered the trainee's progress such as harassment, the COVID-19 pandemic, or other personal or professional circumstances

Current Status

- Trans-NIH committee refining, clarifying wording
- **RFI planned: ~February 2023**

More information:

- Final report of the CSRAC Working Group on Fellowship Review
- Videocast presentation of the final report to the full CSR Advisory Council, September 2022

Discussion