Simplified Review Framework

Research Project Grants (RPG)

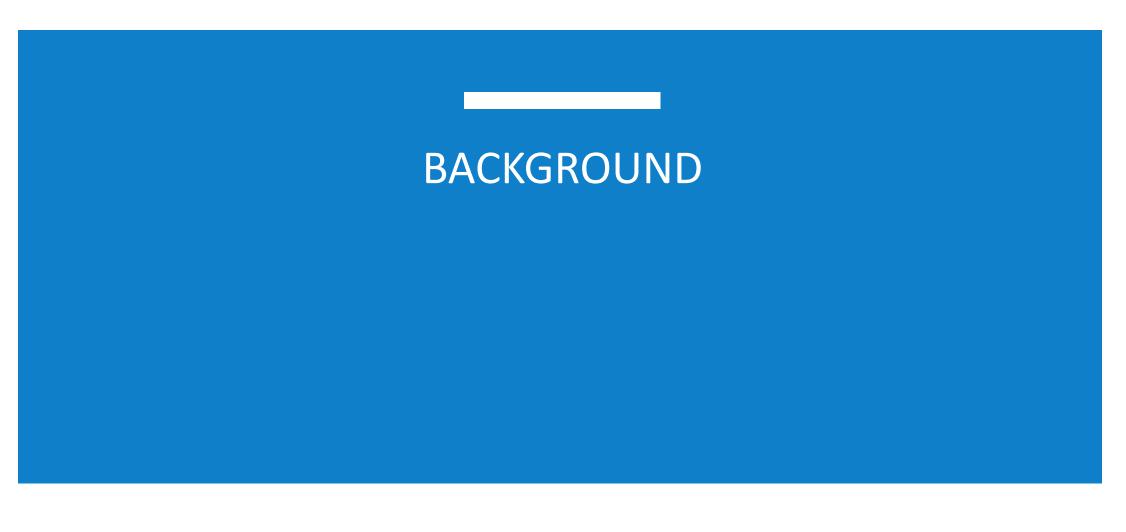
An Update | September 18, 2023 | Mark Caprara, CSR; Brian Hoshaw, NEI; Lisa Steele, CSR



Overview of What's Changing: Big Picture

- **1**. Reorganize the existing five review criteria into three factors
- 2. Investigator and Environment will be evaluated as sufficient or gaps identified (considered in overall impact score, but no criterion score)
- 3. Changes to Additional Review Criteria for more rigorous review of human subjects research
- 4. Reduce the number of Additional Review Considerations for reviewers to assess





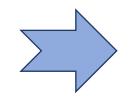


Motivation for change

- 1. Peer review criteria had become too complex, too numerous
 - Persistent feedback from reviewers and observed by OER/CSR
 - Expansion of administrative and policy-compliance aspects in peer review
- 2. Undue influence of reputation in NIH peer review
 - Concerns from the community
 - CSR's "anonymization" study suggested halo effects benefit white investigators
 - NIH review is vulnerable to this bias because CFR requires evaluation of investigator and environment



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



Affects judgments of merit by giving big names a pass and unknowns extra scrutiny



Extramural and trans-NIH input

JAN '20- MAR '20 - CSR Advisory Council Working Group 1

MAR '20 – Interim report presented to full CSR Advisory Council – approved general framework.

SEPT '20 – FEB '21 – CSR Advisory Council Working Group 2 (Clinical Trials Focus)

MAR '21 – Final set of recommendations approved by full CSR Advisory Council

JUL '21 – Presentation of CSRAC recommendations to Extramural Activities Working Group (EAWG) → wellreceived, recommended formation of EAWG Working Group on Simplifying Review Criteria for further consideration

OCT '21 - FEB '22 - EAWG Working group on Simplifying Review Criteria

FEB '22 – EAWG Working Group recommendations approved by full EAWG

APR '22 – EAWG recommendations/framework approved by NIH Steering Committee and Institute/Center Directors







Five regulatory criteria reorganized into three factors

Current

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

Simplified Framework (all considered in Overall Impact Score)

• Factor 1: Importance of the Research

- Significance, Innovation
- Scored 1-9

Factor 2: Rigor and Feasibility

- Approach (also include Inclusions HS and CT Study Timeline)
- Scored 1-9

• Factor 3: Expertise and Resources

- Investigators, Environment
- <u>E</u>valuated as appropriate or gaps identified; gaps require explanation
- Considered in overall impact; no individual score



Reduced Additional Review Considerations

Most Additional Review Considerations **removed** from first-level peer review; responsibility will shift to awarding institute/center

Current	Simplified Framework
Additional Review Considerations	Additional Review Considerations
(no effect on overall impact score)	(no effect on overall impact score)
 Applications from Foreign Organizations Select Agent Research Resource Sharing Plans Authentication of Key Biological and/or	 Authentication of Key Biological and/or
Chemical Resources Budget and Period of Support	Chemical Resources Budget and Period of Support



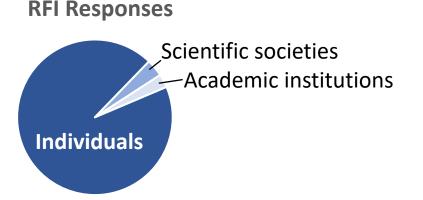




Implementation began with Request for Information (RFI) December 2022

800 responses

- 780 individuals
- 30 scientific societies
- 23 academic institutions



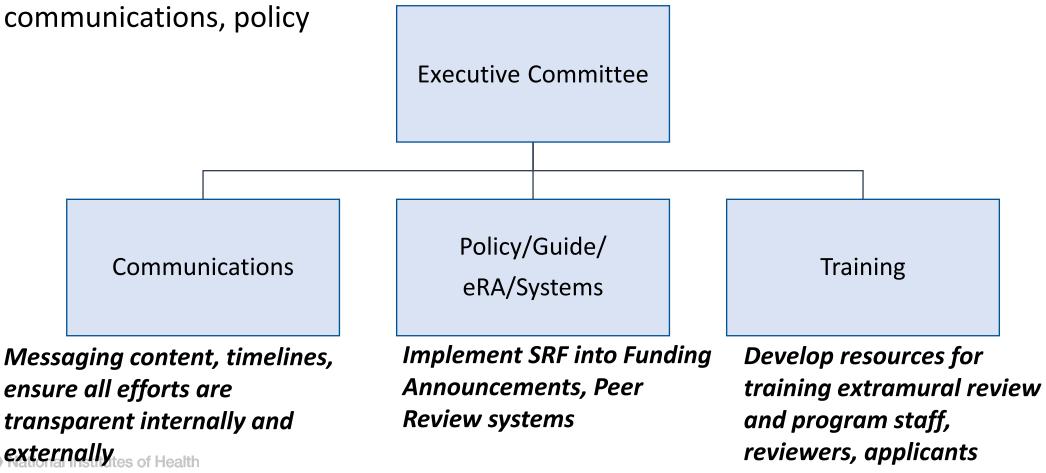
- Majority of respondents were very supportive of proposed changes not surprising given that the framework was developed with significant input from the extramural community
- Recommendations regarding Implementation:
 - Strong training resources to align reviewers, study section chairs, and SROs

Full report: NIH SRF RFI Content Analyses April 2023 508c.pdf



Simplifying Review Framework (SRF) Implementation Committee

Trans-NIH implementation committee with deep, multidimensional domain expertise in peer review, reviewer training, staff training, eRA systems,



SRF Implementation Committee

A Few Key Areas of Early Focus for the Committee:

- a) Establish an efficient framework for coordination and communication of SRF implementation activities with NIH Institutes (ICs)
- b) Strategic planning and coordination of communications to internal and external communities during implementation
- c) RPG Funding Announcements must contain the new Review Framework--requires reissuing hundreds of Announcements



Framework for coordination and communication of SRF implementation activities with NIH ICs

Each IC has identified 2 central coordinators to facilitate implementation activities at their respective organization.

Responsibilities:

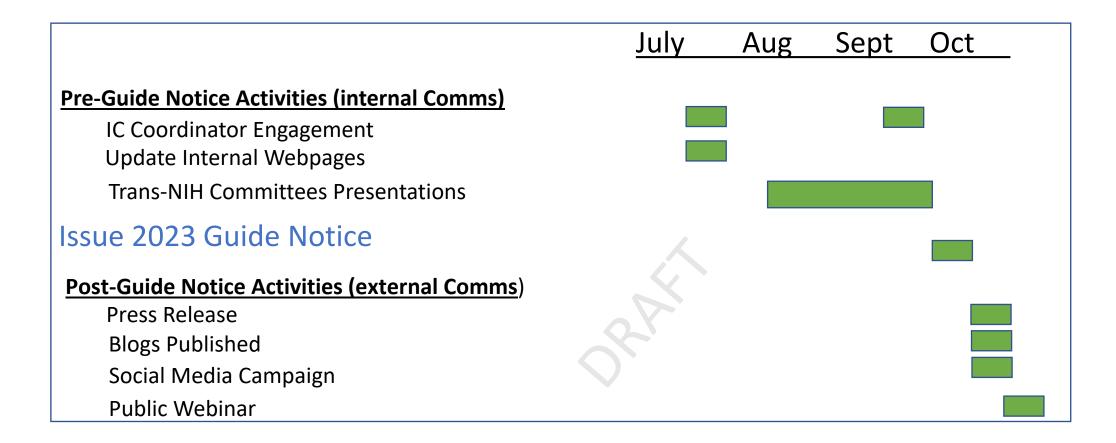
- Facilitating communications to and from the Implementation Committee
- Communicating and coordinating implementation activities
- Providing input on needed resources
- Distribution of relevant training and informational resources
- Relaying issues and challenges in implementation activities

Efficient and transparent implementation efforts across NIH



Precise Planning for Communications

Timeline for Guide Notice Publication Notifying Public of the Final SRF Language and Implementation Date

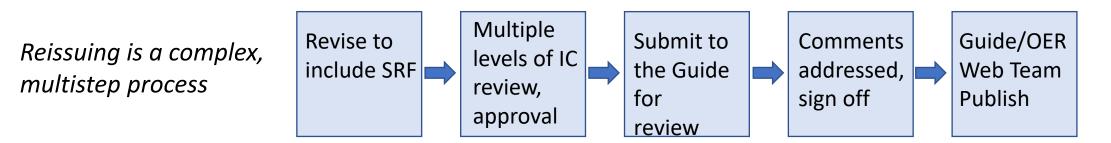


NIH

National Institutes of Health Turning Discovery Into Health

Coordinated and Comprehensive Communication with Internal and External Communities

RPG Funding Announcements must contain the new Review Framework (requires re-issuing hundreds of funding announcements)



A pilot is planned for a limited number of Funding Announcements to through the reissue process

- Gives ICs the opportunity to (potentially) streamline their internal processes (increase efficiency for rollout)
- Discover and address any unanticipated problems

Goal is to inform planning of SRF reissue rollout, ease burden on IC and Guide staffs, make it as efficient as possible, leading to timely publication for applicant community



When will the new framework be implemented?

- Applications submitted for January 25, 2025 due dates
- Summer 2025 peer review
- October 2025 Advisory Council

Scope

• All RPGs (eg R01, R21 etc) excluding those that use nonstandard review criteria.



Next Steps: Between Now and January 2025

Fall 2023:

- Issue Guide Notice announcing changes
- Public webinar providing an overview of changes
- Staff webinar providing overview of changes and timeline for implementation

Over the next year:

- Changes to eRA systems
- Developing resources and training for NIH staff, reviewers, and applicants
- Updating and publishing funding opportunities

Lots of training and outreach to applicants, reviewers, and NIH staff!



Simplifying Review Framework Implementation Executive Committee (RPGs)

Co-Chairs



Mark Caprara CSR



Brian Hoshaw NEI



Lisa Steele CSR

National Institutes of Health

Turning Discovery Into Health



Members

Erica Brown NIGMS



Kasima Garst OER



Michelle Bulls OER

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CSR





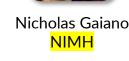
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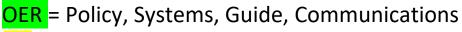
Sara Silver OER

Tracy Waldeck NIMH









- ICs = Review, Extramural Activities, Program, Training
- **CSR** = Review, Training, Communications

