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
BACKGROUND
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

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
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<tbody>
<tr>
<td>JAN ‘20–MAR ‘20</td>
<td>CSR Advisory Council Working Group 1</td>
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<tr>
<td>MAR ‘20</td>
<td>Interim report presented to full CSR Advisory Council – approved general framework.</td>
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<tr>
<td>SEPT ‘20–FEB ‘21</td>
<td>CSR Advisory Council Working Group 2 (Clinical Trials Focus)</td>
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<td>MAR ‘21</td>
<td>Final set of recommendations approved by full CSR Advisory Council</td>
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<td>JUL ‘21</td>
<td>Presentation of CSRAC recommendations to Extramural Activities Working Group (EAWG) → well-received, recommended formation of EAWG Working Group on Simplifying Review Criteria for further consideration</td>
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<td>OCT ‘21–FEB ‘22</td>
<td>EAWG Working group on Simplifying Review Criteria</td>
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<tr>
<td>FEB ‘22</td>
<td>EAWG Working Group recommendations approved by full EAWG</td>
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<tr>
<td>APR ‘22</td>
<td>EAWG recommendations/framework approved by NIH Steering Committee and Institute/Center Directors</td>
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OVERVIEW OF CHANGES
Five regulatory criteria reorganized into three factors

| **Current** | **Simplified Framework**
| --- | --- |
| • Significance - scored | (all considered in Overall Impact Score)
| • Investigator(s) – scored | **Factor 1: Importance of the Research**
| • Innovation – scored | • Significance, Innovation
| • Approach – scored | • Scored 1-9
| • Environment - scored | **Factor 2: Rigor and Feasibility**
| | • Approach (also include Inclusions HS and CT Study Timeline)
| | • Scored 1-9
| | **Factor 3: Expertise and Resources**
| | • Investigators, Environment
| | • Evaluated as appropriate or gaps identified; gaps require explanation
| | • Considered in overall impact; no individual score
Most Additional Review Considerations **removed** from first-level peer review; responsibility will shift to awarding institute/center

<table>
<thead>
<tr>
<th>Current</th>
<th>Simplified Framework</th>
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<tr>
<td><strong>Additional Review Considerations</strong></td>
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<tr>
<td>(no effect on overall impact score)</td>
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<tr>
<td>• Applications from Foreign Organizations</td>
<td>• Authentication of Key Biological and/or Chemical Resources</td>
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<tr>
<td>• Select Agent Research</td>
<td>• Budget and Period of Support</td>
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<tr>
<td>• Resource Sharing Plans</td>
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<tr>
<td>• Authentication of Key Biological and/or Chemical Resources</td>
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<td>• Budget and Period of Support</td>
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IMPLEMENTATION EFFORTS
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, communications, policy.

- Executive Committee
- Communications
- Policy/Guide/eRA/Systems
- Training

Messaging content, timelines, ensure all efforts are transparent internally and externally.

Implement SRF into Funding Announcements, Peer Review systems.

Develop resources for training extramural review and program staff, reviewers, applicants.
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 re-issuing 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

<table>
<thead>
<tr>
<th>Pre-Guide Notice Activities (internal Comms)</th>
<th>July</th>
<th>Aug</th>
<th>Sept</th>
<th>Oct</th>
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<tr>
<td>IC Coordinator Engagement</td>
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<td>Update Internal Webpages</td>
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<td>Trans-NIH Committees Presentations</td>
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**Issue 2023 Guide Notice**

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<tr>
<th>Post-Guide Notice Activities (external Comms)</th>
<th>July</th>
<th>Aug</th>
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<tr>
<td>Press Release</td>
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<td>Blogs Published</td>
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<td>Social Media Campaign</td>
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<td>Public Webinar</td>
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**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)

Reissuing is a complex, multistep process

- Revise to include SRF
- Multiple levels of IC review, approval
- Submit to the Guide for review
- Comments addressed, sign off
- Guide/OER Web Team Publish

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 non-standard 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)
- Kristin Kramer (CSR)
- Miriam Mintzer (CSR)
- Aaron Czaplicki (OER)

Members
- Erica Brown (NIGMS)
- Michelle Bulls (OER)
- Megan Columbus (OER)
- Aaron Czaplicki (OER)
- Nicholas Gaiano (NIMH)
- Brian Hoshaw (NEI)
- Kasima Garst (OER)
- Kristin Kramer (CSR)
- Valerie Maholmes (NICHD)
- Miriam Mintzer (CSR)
- Laurie Roman (OER)
- Lisa Steele (CSR)
- Marci Scidmore (NIAID)
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- Sara Silver (OER)
- Tracy Waldeck (NIMH)
- Mark Caprara (CSR)
- Kasima Garst (OER)
- Lisa Steele (CSR)
- Marci Scidmore (NIAID)

Project Manager
- Lia Fleming (CSR)
- Stephanie Constant (OER)

Review Policy Officer
- Laurie Roman (OER)

OER = Policy, Systems, Guide, Communications
ICs = Review, Extramural Activities, Program, Training
CSR = Review, Training, Communications