The Role of Program Directors (PDs) in the Grants Process

Chamelli Jhappan Ph.D.

Program Director, Cancer Immunology, Hematology and Etiology Branch (CIHEB), Division of Cancer Biology (DCB), NCI, NIH

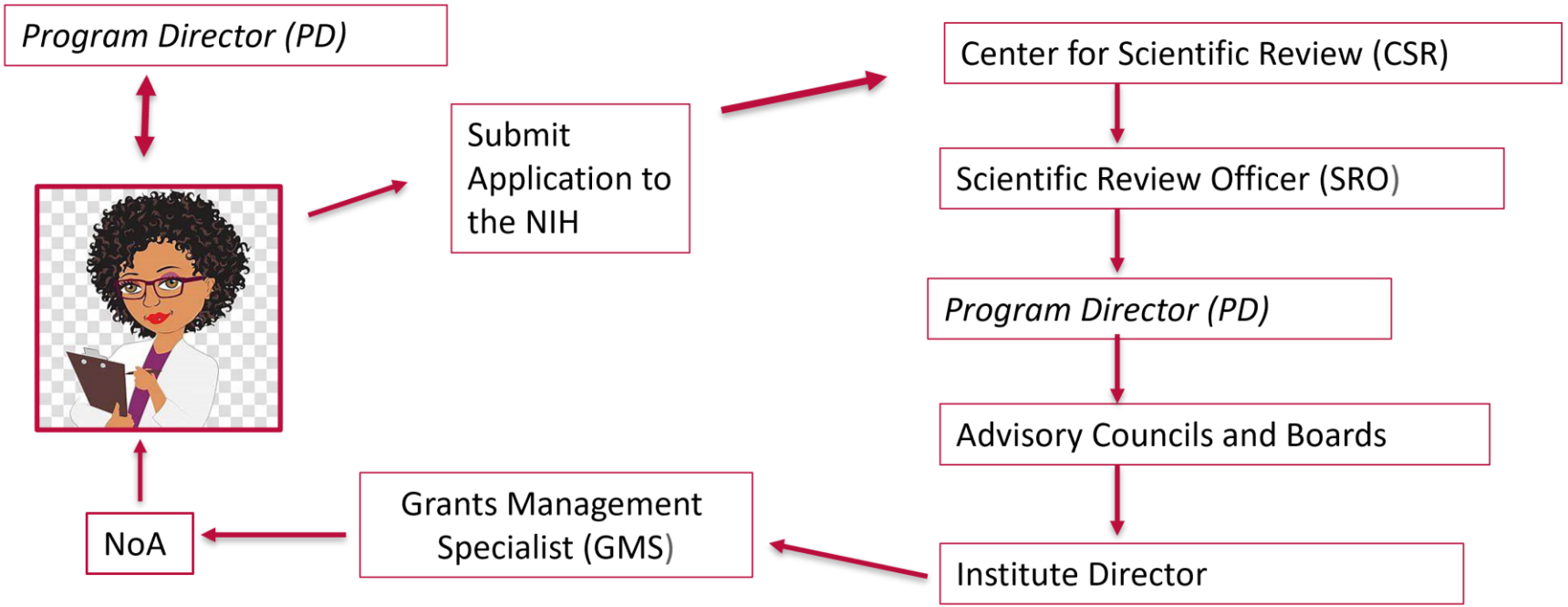
NIH NATIONAL CANCER INSTITUTE

March 13, 2024

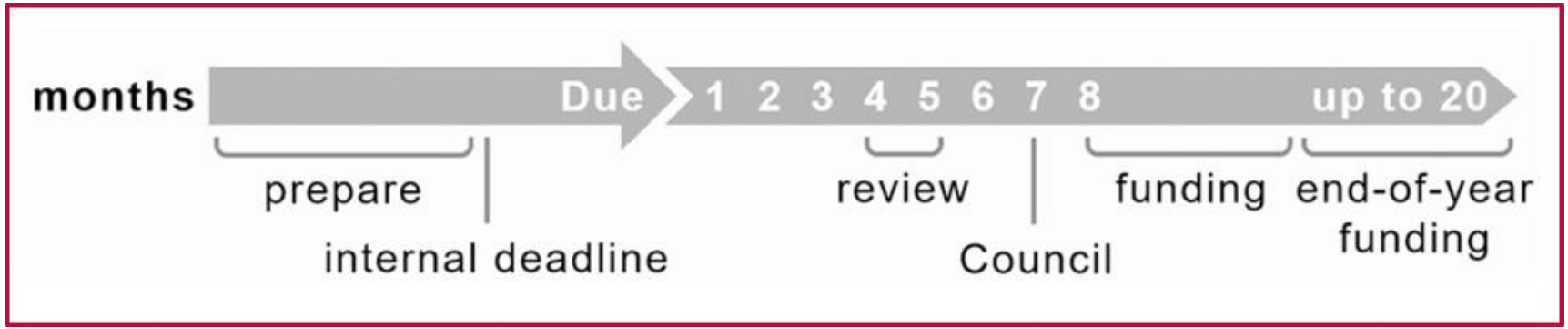
Program Director (PD)

- Manage portfolio of grants within scientific area of interest
- Oversee scientific and technical aspects of grants
- Review annual progress made on grant
- Stewards of taxpayers' funds ensuring that scientific investments are maximized and used to fullest potential
- Foster excellent science and promote effective communication and collaboration
- Identify scientific opportunities, gaps in portfolio, future directions or trends in science

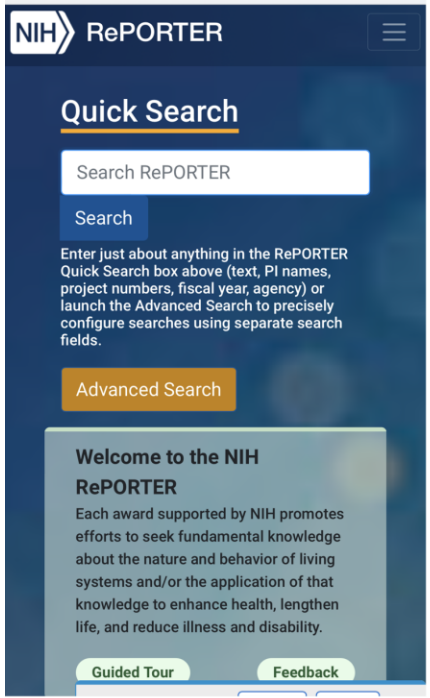
The NIH Grant Cycle: Connecting PDs and PIs

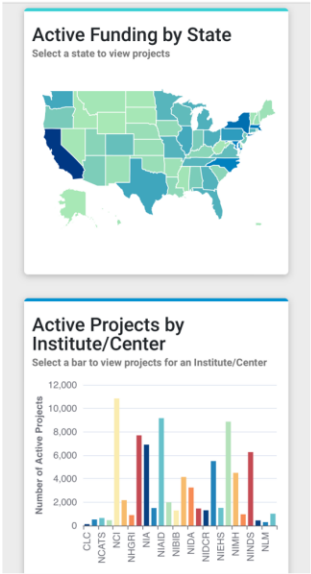


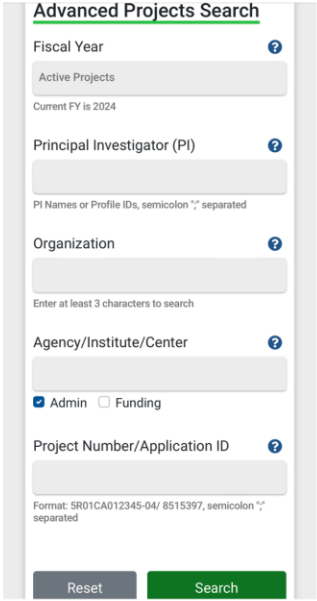
Getting Started…Overall Timeline for NIH Grant Process

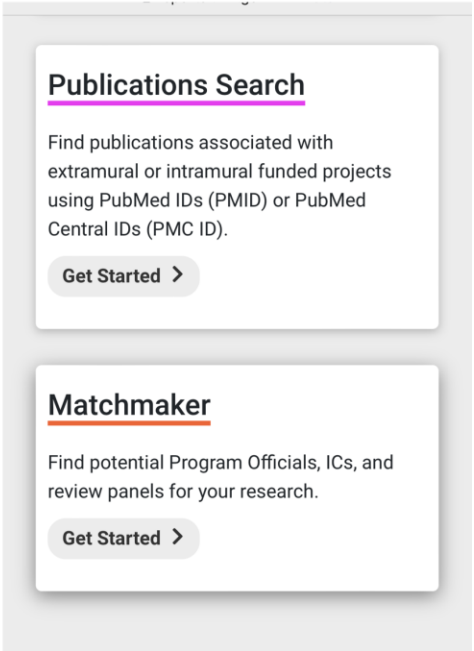


NIH Reporter





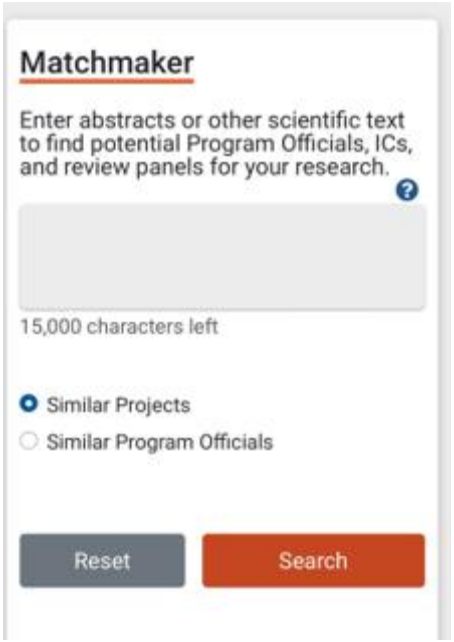




https://reporter.nih.gov

Matchmaker & Assisted Referral Tool (ART)

Matchmaker Tool



NIH Reporter

Assisted Referral Tool

[Assisted Referral Tool (ART) NIH Center for Scientific Review]

What will your first discussion with a PD look like?

- Do you have a Specific Aims page?
- Be sure you have all your preliminary prior to submission
- Make sure your Aims are not interdependent
- Develop hypotheses and be careful how you word them
- Ask the PD and colleagues to give you feedback on your aims page

Limits to what any PD can do….

PDs *cannot*:

- Provide exemptions for submission deadline
- Change a study section assignment
- Change the NCI funding policy
- Change the fulfillment requirements for an award to be issued
- Write you a letter of recommendation as your PD
- Break confidentiality (cannot talk to your Chairman, write recommendations discuss you job or summary statement with anyone

PDs and PIs can learn from each other…..

THANK YOU!

www.cancer.gov

www.cancer.gov/espanol

U.S. Department of Health & Human Services

NIH Center for Scientific Review

Peer Review at NIH

Dr. Amy Rubinstein
Chief, Basic and Translational Cancer (BTC) Review Branch

NCI Transition Career Development Workshop
January 2024

Review and Funding of NIH Grant Applications - Timeline

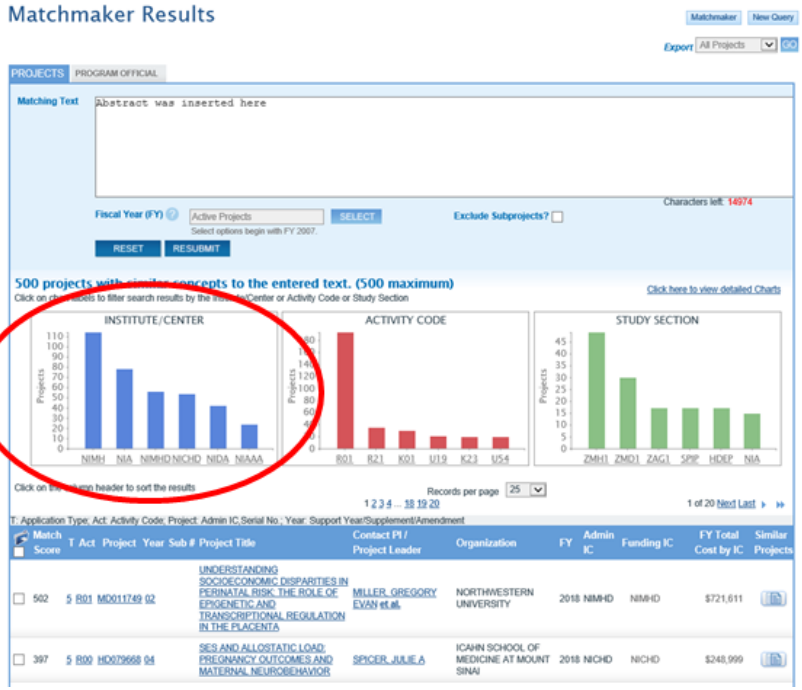
Center for Scientific Review *Division of Receipt and Referral*	**Level I Review:** *Study Section*	**Level II Review:** *Institute or Center*
Assigns to Institute(s) and Review Group *2 weeks*	SRO Recruits and Assigns Reviewers *2-4 weeks*	Evaluates Relevance to Research Priorities
	Reviews for Scientific Merit *4-6 weeks*	Council Recommends Action
	Meets *1-2 days*	Funding Decision by IC Director *2-4 months*
	Score Release *~3 days*	
	SRO Produces Summary Statement *~30 days*	

Applications Are Assigned to:

- **Institutes or Centers based on**
  - Overall mission and guidelines of the IC
  - Specific programmatic mandates and interests of the IC
  - Applications can only be assigned to ICs participating in the FOA

- **Scientific review groups based on**
  - Specific, published review guidelines for each review group
  - Suggestions made in the Assignment Request Form are considered

Help Your Application Get to the Right Institute



- Copy abstract/Aims
- Matchmaker Search returns:
  - List of Institutes
  - List of funded grants
  - Link to Program Officials

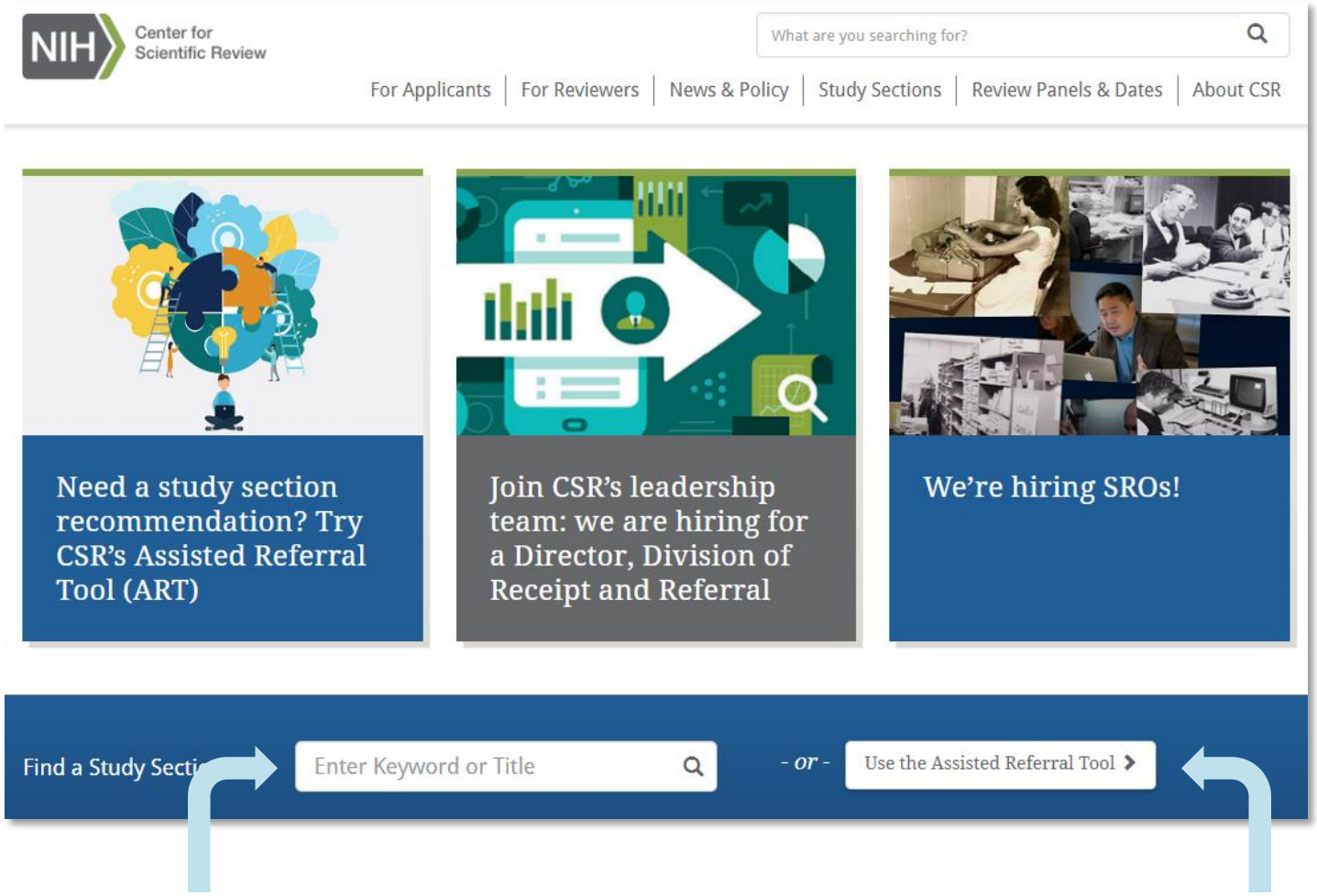
Assignment Request Form (ARF)

The ARF replaces many functions of the cover letter.
Use it to:

- Make assignment suggestions (study section and institute)
- Identify potential conflicts of interest
- List areas of expertise needed to evaluate the application

You should never suggest specific reviewers

What study sections might you suggest?



Keyword search

Assisted Referral Tool (ART)

http://www.csr.nih.gov

Assignment to CSR Study Sections

Within a Review Branch, applications are assigned to:

Standing Study Sections

- When subject matter of application matches the referral guidelines for the study section or

Special Emphasis Panels (SEPs)

- When the subject matter does not fit into any study section—recurring or for one-time conflicts or initiatives.
- When assignment of an application to the most appropriate study section creates a conflict of interest
- When certain types of grants are sought (e.g., fellowships, SBIRs, AREAS)

Reviewer Conflicts of Interest (COI)

What constitutes a reviewer COI?

- Institutional
- Family member/close friend
- Collaborator/Key Personnel
- Longstanding scient ific disagreement
- Personal bias
- Appearance of conflict

http://grants.nih.gov/grants/peer/peer_coi.htm

Confidentiality

- Review materials and proceedings of review meetings represent confidential information for reviewers and NIH staff.
- At the end of each meeting, reviewers must destroy or return all review-related material.
- Reviewers should not discuss review proceedings with anyone except the SRO.
- Questions concerning review proceedings should be referred to the SRO.
- Applicants should never communicate directly with any members of the study section about an application.
- Statute of confidentiality is life-long.

Peer Review Integrity Issues

- For concerns or questions about possible violations of peer review integrity contact:
  - Your Scientific Review Officer
  - CSR Review Integrity Officer at: csrrio@mail.nih.gov
  - NIH Review Policy Officer at: reviewpolicyofficer@mail.nih.gov
- For issues related to respectful interactions, bias or anything else that could affect the fairness of the review process, contact your SRO or send a message to reportbias@csr.nih.gov.

Before the Study Section Meeting

Each application is assigned to 3 or more reviewers 5-6 weeks in advance

Reviewers Assess Each Application by Providing:

Preliminary Overall Impact score

- Criterion scores
- Comment on appropriateness of your budget
- A written critique

Changes Coming:
Simplified Framework for NIH Peer Review

Goals:

1. Enable peer reviewers to better focus on answering the key questions necessary to assess scientific and technical merit
   - Should the proposed research project be conducted?
   - Can the proposed research project be conducted?

2. Mitigate the effect of reputational bias
3. Reduce reviewer burden

When?

Applies to most research project applications submitted for January 25, 2025, due dates. Check the Guide Notice for specific details.

Guide Notice
NOT-OD-24-010

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

1. **Improve reviewer focus**
   - Existing five review criteria reorganized into three factors
   - Some Additional Review Criteria (inclusions, study timeline) related to human subjects moved to Factor 2
2. **Reduce reputational bias**
   - Investigator/Environment will be evaluated as sufficient or gaps identified (considered in overall impact score, but no individual score)
3. **Reduce reviewer burden**
   - Most Additional Review Considerations shifted from reviewers to NIH staff

Improve identification of the strongest, potentially highest-impact research

The Simplified Review Framework Reorganizes Five Regulatory Criteria into Three Factors

Before January 25, 2025

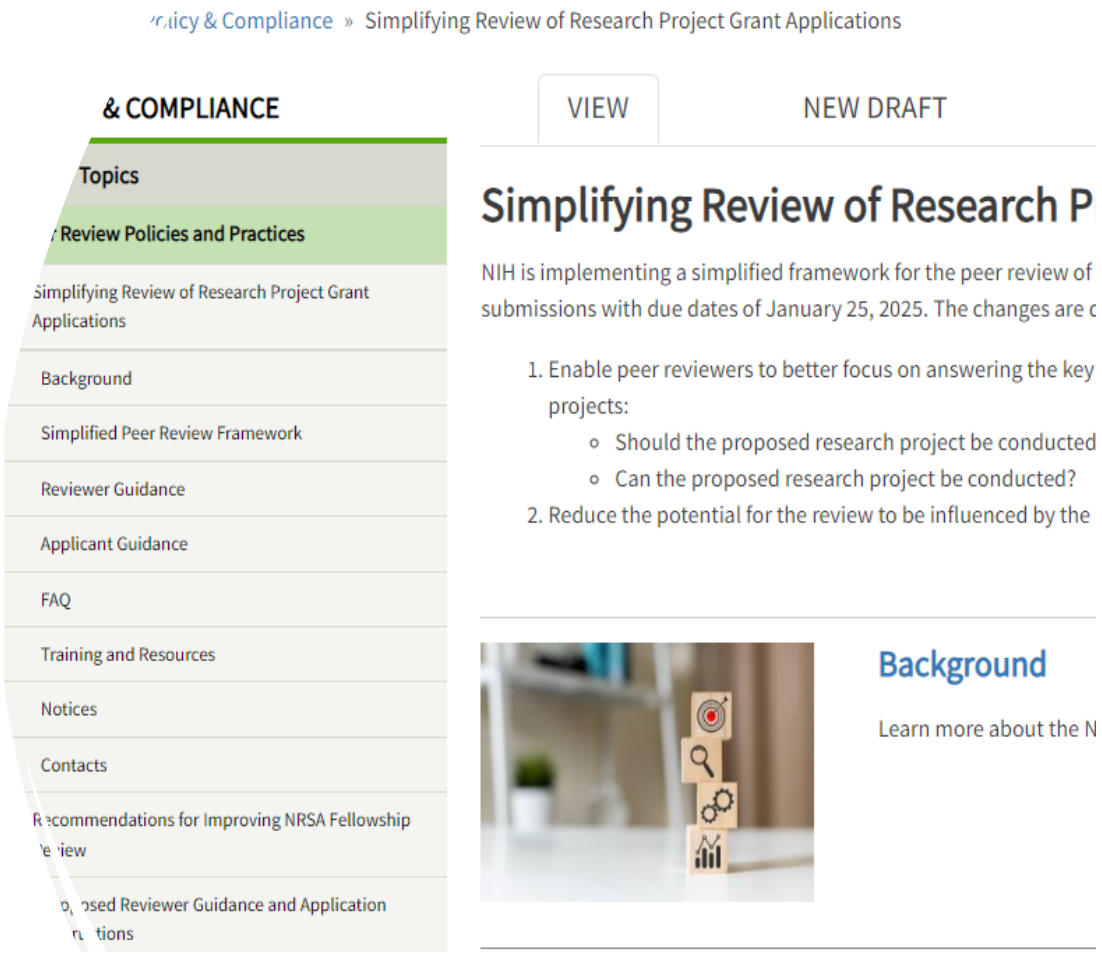
- Significance - scored
- Investigator(s) – scored
- Innovation – scored
- Approach – scored
- Environment - scored

On or after Jan 25, 2025 - 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 and Study Timeline for clinical trials*)
  - **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**

Learn More & Stay Informed

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



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

At the Meeting

Not Discussed Applications

- About half the applications will be discussed
- Applications unanimously judged by the review committee to be in the lower half are not discussed

Clustering of Review

- New Investigator R01 & some types of applications are often reviewed together

Order of Review

- Applications to be discussed are reviewed in random order within each cluster.

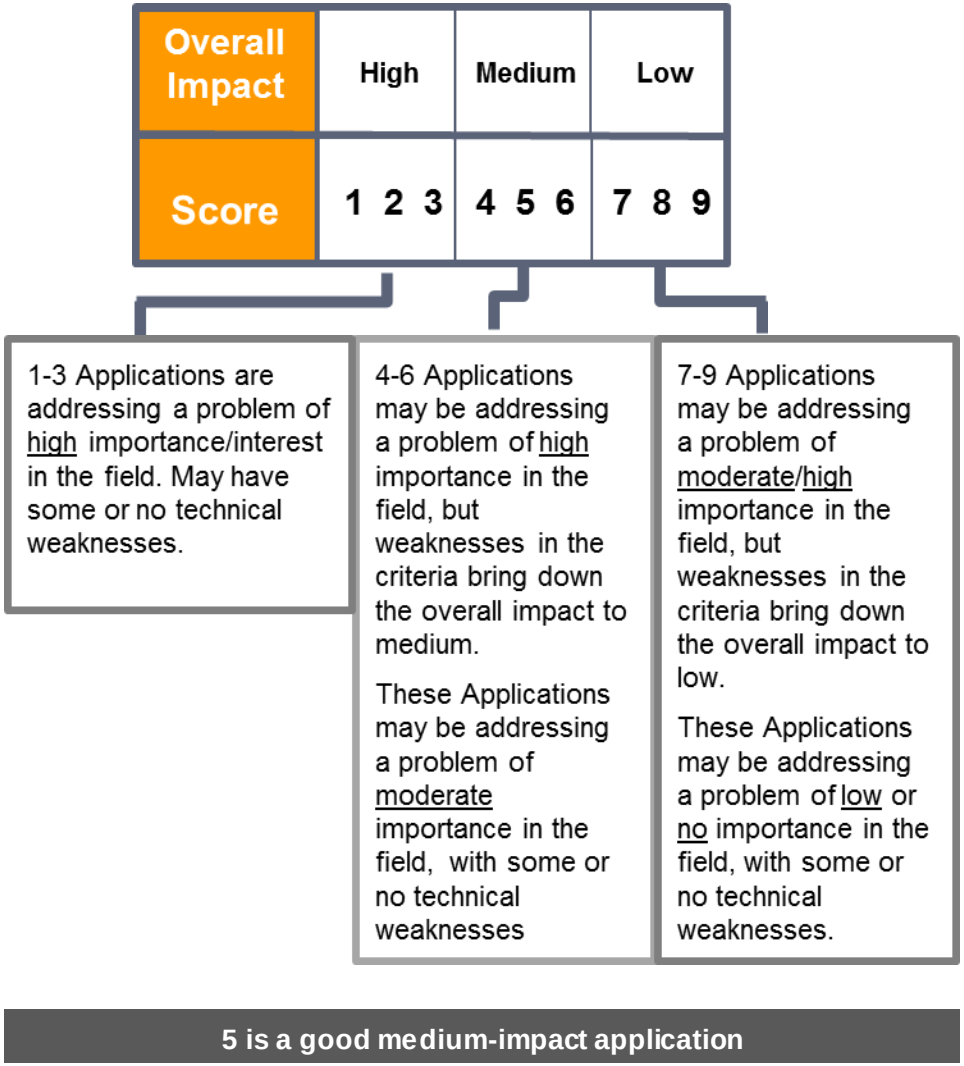
At the Meeting: Application Discussion

- Any member in conflict with an application leaves the room
- Reviewer 1 introduces the application and presents critique
- Reviewers 2 and 3 highlight new issues and areas that significantly impact scores
- All members without a conflict are invited to join the discussion and then vote on the final overall impact score

Scoring Overall Impact

Overall Impact:
The likelihood for a project to exert a sustained, powerful influence on research field(s) involved

Evaluating Overall Impact:
Consider the 5 criteria: significance, investigator, innovation, approach, environment (weighted based on reviewer's judgment) and other score influences, e.g. human subjects



NIH's Resubmission Policy

After an unsuccessful new (A0) application or an unsuccessful resubmission (A1) application, you may submit a new (A0) application with the same idea as long as your summary statement has been issued.

The NIH Will Not Accept:

- An A0 or A1 application that overlaps a funded application
- Simultaneous submissions of overlapping applications
- An A0 or A1 application before NIH issues the summary statement of an earlier, overlapping application.

Resubmission FAQs

http://grants.nih.gov/grants/policy/resubmission_q&a.htm

Your New Application Must Be Written as New

Your new (A0) application should not contain information that might bias the review or provide a competitive advantage:

You Cannot Refer to a Previous Review

- No mention of previous score
- No mention of previous reviewer comments
- No mention of how the A0 is responsive to previous review
- No marks in text to indicate changes

You Cannot Submit Elements of a Renewal

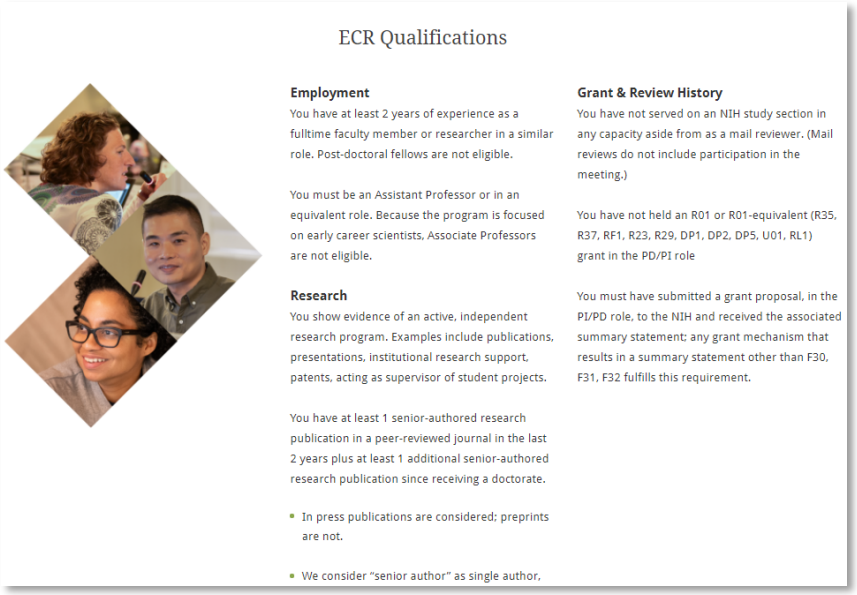
- No Progress Report
- No Progress Report Publication List

Where Do We Find Reviewers?

- Successful applicants
- Recommendations from reviewers and NIH staff
- NIH RePORTER (http://projectreporter.nih.gov/reporter.cfm)
- NIH PI and reviewer databases
- Internet
- Scientific conferences

Serve on a Review Panel

- Early career scientists can enroll in CSR's early career reviewer (ECR) program.
- ECR's serve one time and review 2 applications as R3.
- Check https://public.csr.nih.gov/ForReviewers/BecomeAReviewer/ECR for qualifications and application process.



ECR Qualifications

Employment
You have at least 2 years of experience as a fulltime faculty member or researcher in a similar role. Post-doctoral fellows are not eligible.

You must be an Assistant Professor or in an equivalent role. Because the program is focused on early career scientists, Associate Professors are not eligible.

Research
You show evidence of an active, independent research program. Examples include publications, presentations, institutional research support, patents, acting as supervisor of student projects.

You have at least 1 senior-authored research publication in a peer-reviewed journal in the last 2 years plus at least 1 additional senior-authored research publication since receiving a doctorate.

- In press publications are considered; preprints are not.
- We consider "senior author" as single author,

Grant & Review History
You have not served on an NIH study section in any capacity aside from as a mail reviewer. (Mail reviews do not include participation in the meeting.)

You have not held an R01 or R01-equivalent (R35, R37, RF1, R23, R29, DP1, DP2, DP5, U01, RL1) grant in the PD/PI role

You must have submitted a grant proposal, in the PI/PD role, to the NIH and received the associated summary statement; any grant mechanism that results in a summary statement other than F30, F31, F32 fulfills this requirement.

- Aimed at early career, independent scientists – postdocs are not eligible and tenured professors are not eligible
- Review experience and successful competition for an R01 or equivalent are disqualifiers.

NIH Peer Review Information on the Web

National Institutes of Health: http://www.nih.gov

- **Office of Extramural Research**
  https://grants.nih.gov/aboutoer/welcome.htm
- **Grants Policy**
  https://grants.nih.gov/policy/index.htm
- **Electronic Submission**
  https://grants.nih.gov/aboutoer/oer_offices/era.htm

Center for Scientific Review: http://www.csr.nih.gov

- **Resources for Applicants**
  http://www.csr.nih.gov/ResourcesforApplicants
- **CSR Study Section Descriptions**
  http://public.csr.nih.gov/StudySections
- **CSR Rosters and Meeting Dates**
  https://public.csr.nih.gov/RevPanelsAndDates