

This webinar is being recorded.

# Q&A Webinar

June 25, 2024 @ 12:00 PM EDT

Please submit your questions in the “Q&A” box  
(scientific inquiries will not be discussed)

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National Institutes of Health  
Office of Strategic Coordination - The Common Fund

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# Q&A Webinar

- Submit questions in the “Q&A” box
- Scientific or situationally specific questions will not be discussed (email us)
- For additional questions, contact us at [PioneerAwards@mail.nih.gov](mailto:PioneerAwards@mail.nih.gov)
- Webinar recording & slides will be posted on website at [commonfund.nih.gov/pioneer](http://commonfund.nih.gov/pioneer)
- For more application guidance, see our Application & Award Guide on website (includes example applications)

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# Panelists

Trish Labosky, Ph.D.

Program Leader  
Office of the Director

James Li, Ph.D.

Scientific Review Officer  
Center for Scientific Review

Becky Miller, Ph.D.

Program Officer  
Office of the Director

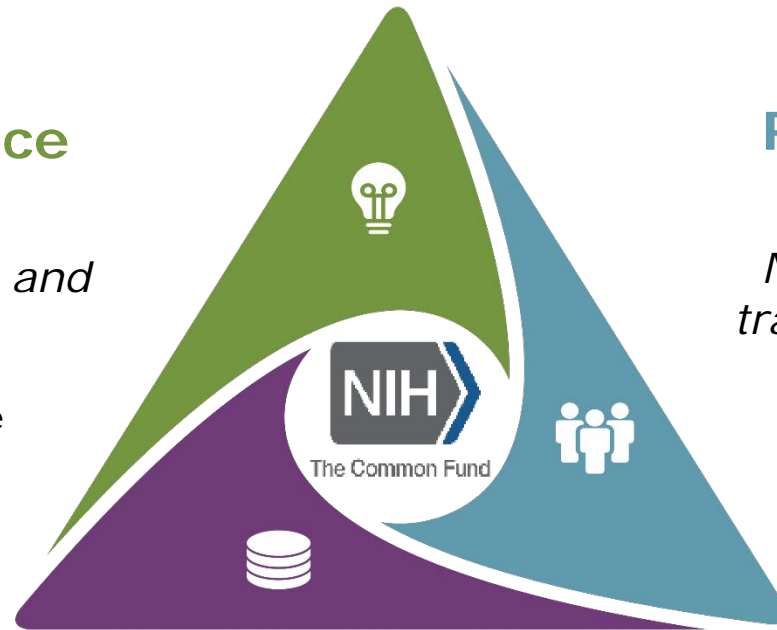
# Breadth of Common Fund Programs

*27 Programs in 3 Broad Categories*

## Transformational Science and Discovery

*New scientific principles, models, and research resources*

- 4D Nucleome
- A2CPS
- CryoEM
- DS-I Africa
- ExRNA
- Global Health
- HRHR
- Human Virome
- IDG
- MoTrPAC
- NPH
- SMaHT
- SPARC
- Oculomics



## Re-Engineering the Research Enterprise

*New approaches to conducting research, translating research into interventions, and supporting a robust workforce*

- ComPASS
- DPC
- FIRST
- SCGE
- UDN
- Complement-AIRE
- Transformative Research to Address Health Disparities and Advance Health Equity

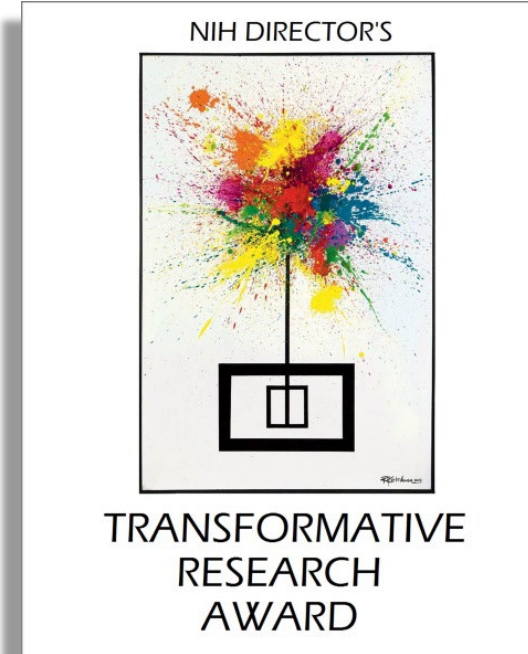
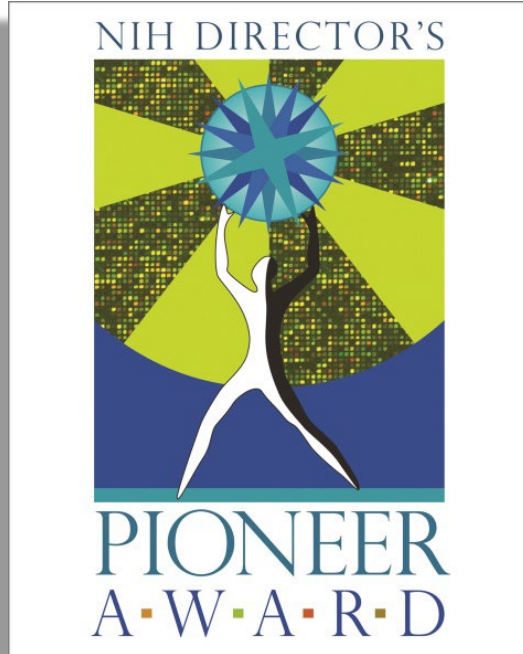
## Catalytic Data Resources

*Data resources to accelerate discovery*

- Bridge2AI
- CFDE
- HuBMAP
- Kids First
- Metabolomics
- SysBio

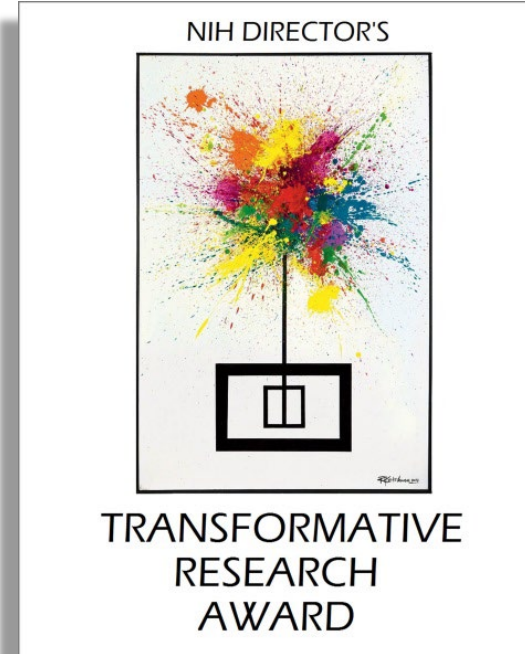
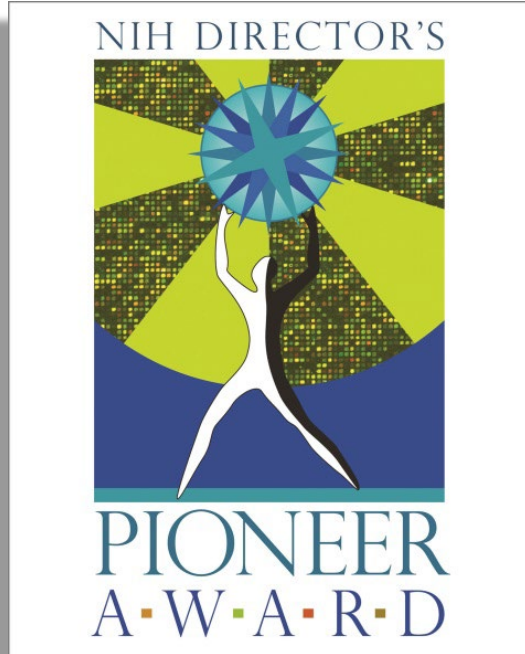
**CF programs may be useful for your research: funding opportunities, access to high-end instruments, databases, reagents, protocols, ....**

# High-Risk, High-Reward Research Program



*Supporting scientists at all career stages proposing outstanding high-risk, high-impact research*

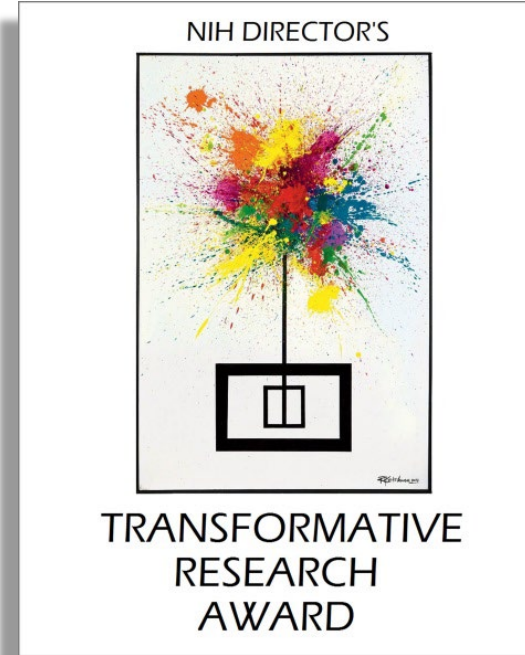
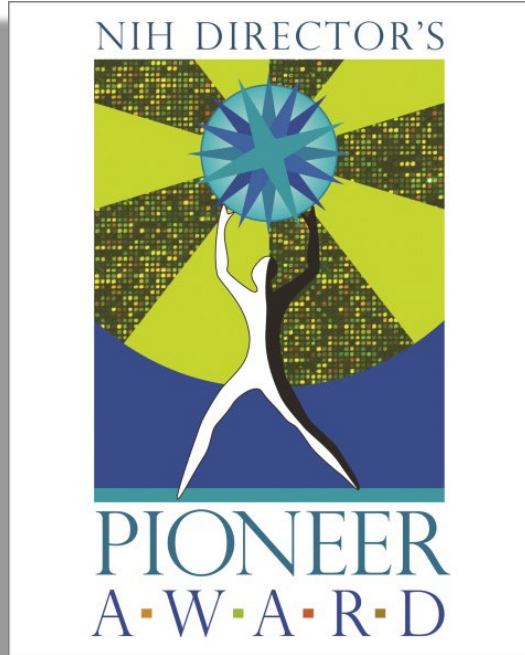
# High-Risk, High-Reward Research Program



Annual funding opportunities

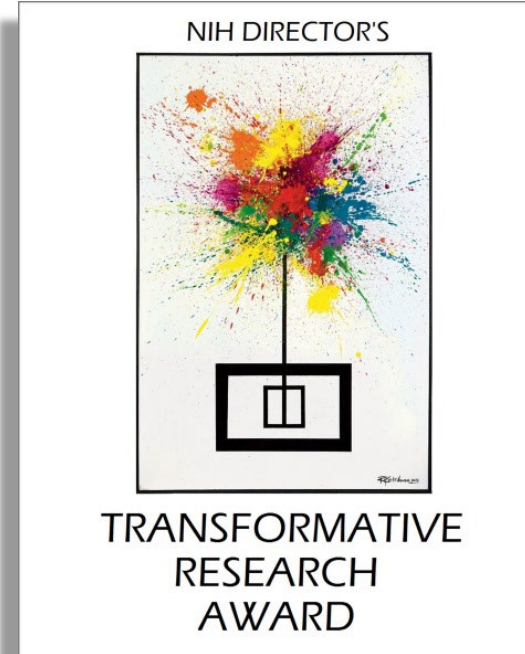
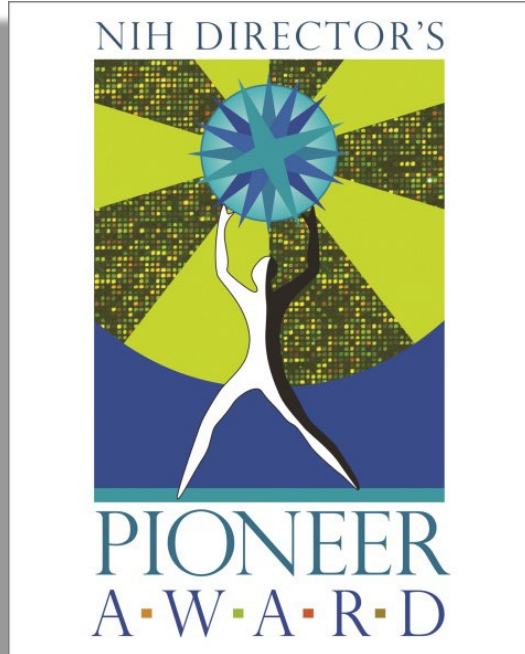


# High-Risk, High-Reward Research Program



High-risk, high-impact ideas

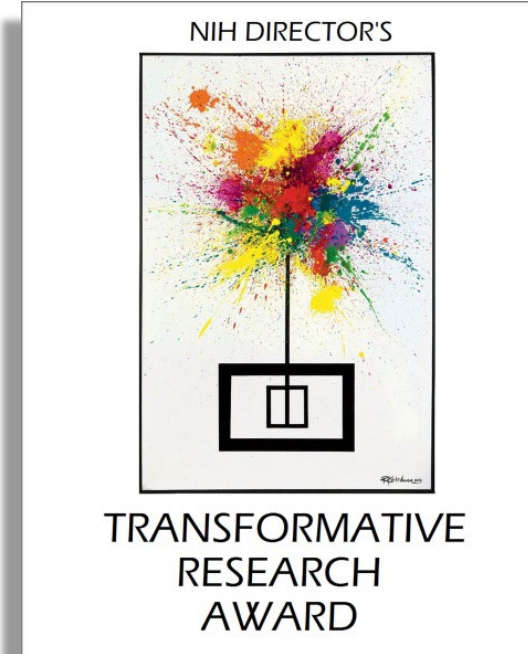
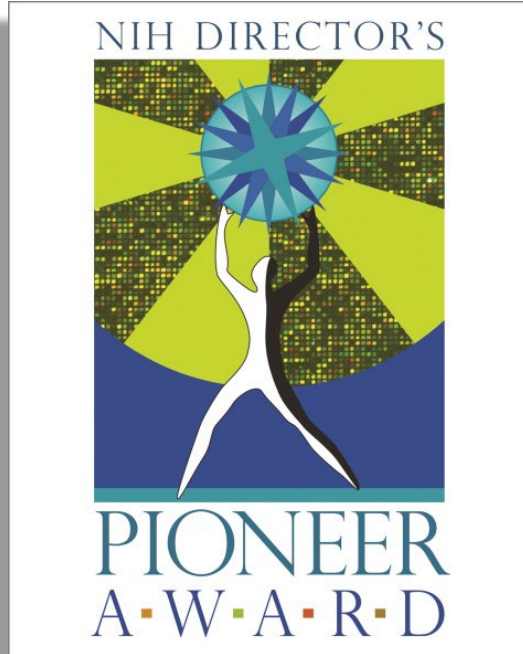
# High-Risk, High-Reward Research Program



No preliminary data or detailed experimental plan required

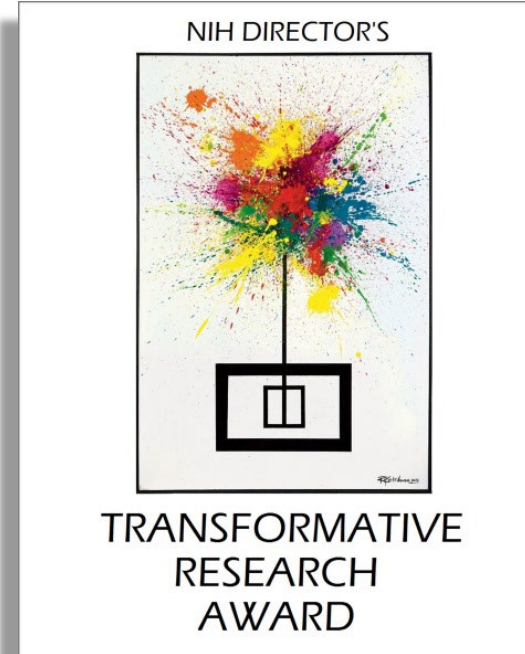
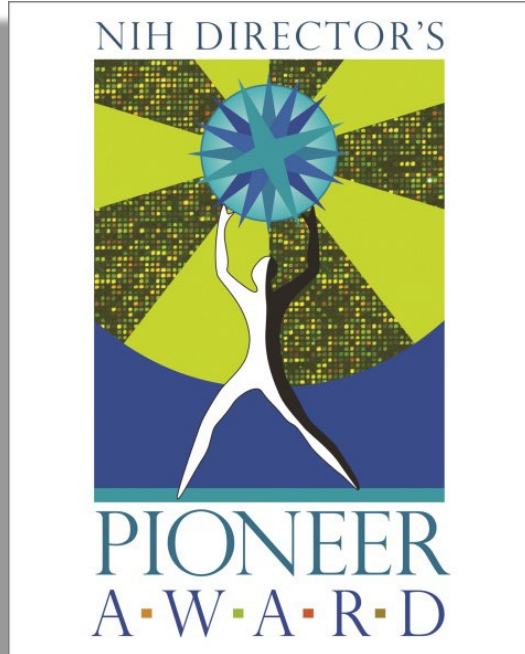


# High-Risk, High-Reward Research Program



*Any topic relevant to NIH mission welcome*  
Behavioral, social, biomedical, applied, and formal sciences,  
and basic, translational, or clinical research

# High-Risk, High-Reward Research Program



Encourage applications from investigators with diverse backgrounds and from the full spectrum of eligible institutions

# HRHR Working Group

## Chair

Tara Schwetz (OD)

## Program Leader

Trish Labosky (OD)

## Members

Kristin Abraham (NIDDK)

Hugh Auchincloss (NIAID)

Geetha Bansal (FIC)

Alexey Belkin (NIAMS)

Sangeeta Bhargava (NEI)

Rebecca Black (OD)

David Bollweg (OD)

Gene Carstea (CSR)

Jennifer Collins (NIEHS)

Christine Colvis (NCATS)

Bill Duval (NINR)

Emmeline Edwards (NCCIH)

Zeynep Erim (NIBIB)

Rene Etcheberrigaray (NIA)

Asanté Forde (OD)

Nancy Freeman (NIDCD)

Brionna Hair (OD)

April Harrison (NIDCR)

Gabriel Hidalgo (NIDCR)

Dana Hill (CSR)

Sharon Isern (CSR)

Ray Jacobson (CSR)

Susan Koester (NIMH)

Trish Labosky (OD)

James Li (CSR)

Roger Little (NIDA)

Brittany Mason-Mah (CSR)

Becky Miller (OD)

Brett Miller (NICHD)

David Miller (NCI)

Michael Morse (OD)

Ellie Murcia (OD)

Imoh Okon (CSR)

Michael Pazin (NHGRI)

Steven Pittenger (NCATS)

Josh Powell (CSR)

Ananda Roy (OD)

Diana Rutberg (NIDCR)

John Satterlee (NIDA)

Dana Schloesser (OD)

Tara Schwetz (OD)

Stefania Senger (CSR)

Doug Sheeley (OD)

Carol Shreffler (NIEHS)

Lillian Shum (NIDCR)

Elena Smirnova (CSR)

Barbara Sorkin (OD)

RV Srinivas (NIAAA)

Nathaniel Stinson (NIMHD)

Meryl Sufian (NLM)

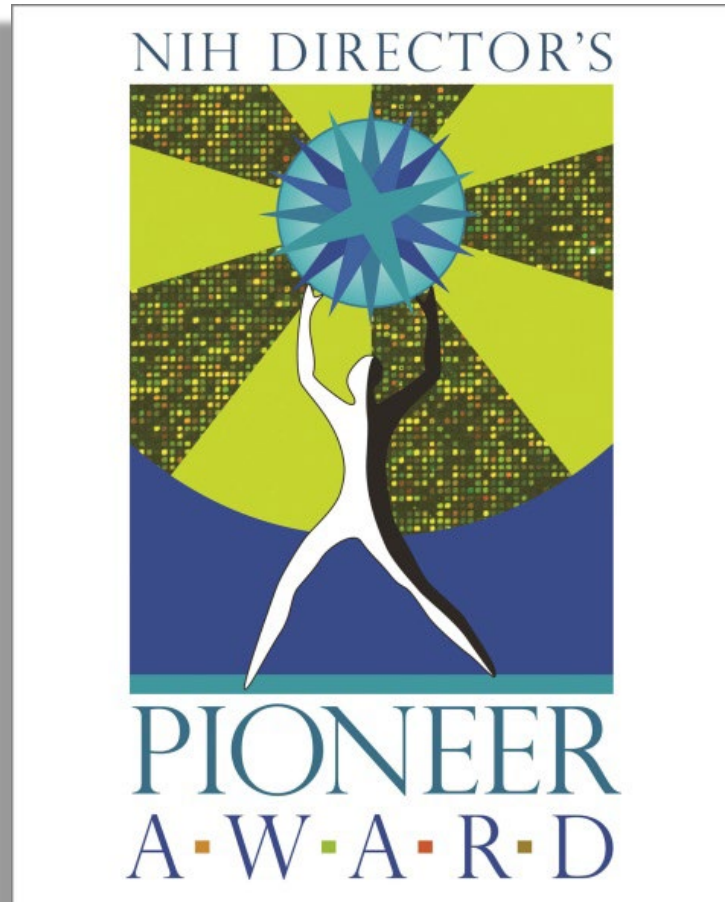
William Tyler (NINDS)

Stephanie Webb (NHLBI)

Ariel Zane (NIGMS)



# High-Risk, High-Reward Research Program



Supports individual scientists with outstanding records of creativity proposing pioneering approaches to major challenges in biomedical and behavioral research

- Started in 2004
- Single PI applications only
- Open to all career stages
- Must be new research direction
- Requires 3 letters of reference
- Commit major portion of research effort (more than 51% for first three years)
- Awards of \$700,000 per year for 5 years

# Pioneer Application

	R01	DP1
<b>Specific Aims page</b>	Required	Do not use
<b>Research Strategy</b>	12 pages including detailed experimental plan and preliminary data	5-page Essay (see later slide for more information)
<b>Biosketch</b>	For all Senior/Key Personnel	For PI only
<b>Bibliography</b>	Required	Do not use; include essential references in Essay
<b>Budget</b>	Details required, esp. for >\$250k direct cost	No detailed budget accepted (indicate only \$3.5M)
<b>Letters of support</b>	Encouraged	Not allowed
<b>Research Effort</b>	Depends on project	At least 51% for first 3 years
<b>Letters of Reference</b>	Not allowed	3 required

# Pioneer Application

Unless specifically directed in the funding opportunity, follow the instructions in the SF424 application guide.

This means that, if appropriate, complete the vertebrate animals section, human subjects section, authentication of key biological and/or chemical resources, ... (These documents do not drive priority scores!)

Complete as best as you can, reviewers will keep in mind that you may have not worked out all the details yet.



# Pioneer Application

In 5 pages, use the following headings or subsections:

- ***Project science areas*** – 1 digit code and abbreviation for primary and secondary areas
- ***Project title*** – descriptive title of proposed project
- ***Project Description*** – Describe scientific importance of topic; overall innovative approach to be taken; preliminary data not required, but accepted; state that to comply with the funding opportunity, a detailed and extensive experimental plan is not being provided; however, provide sufficient evidence that proposal has been deeply considered and will be pursued in a robust and rigorous manner
- ***PI's Innovativeness*** – Provide evidence of a history of high innovation
- ***Change in research direction*** – Explain how proposed project is a change in research direction
- ***Suitability for Pioneer Award program*** – Describe why proposal is “HRHR” rather than traditional
- ***Research effort commitment*** – Commit at least 51% research effort toward project
- ***Bibliography/citations*** – Not required, but encouraged to include critical citations; may be in an abbreviated form as long as identifier is unique

# Pioneer Research Strategy Essay

## Points to consider:

- Given review process used, be sure that what you write can be easily appreciated by people well outside the field for exceptional innovation and potential for unusually broad impact
- May be helpful to begin with a description of the landscape of the field and current state-of-the-art or boundaries; provide proper context for proposal and why what you are proposing is so innovative and potentially impactful
- Ease the reader into the jargon of the field
- Though no data or detailed experimental plan are required, convince the reviewer that you have thought deeply about the project – identify risky aspects, how they will be mitigated, alternate approaches
- Also, convince the reviewer that the research will be performed in a robust and rigorous manner – validate new approaches, provide estimates of numbers of human or animal subjects (if used) and why, include that sex will be considered as a biological variable (if appropriate)

# Data Management & Sharing Plans

Plans should explain how scientific data generated by the research project will be managed and which scientific data and metadata will be shared

- Attach in “Other Plan(s)” section in “PHS 398 Research Plan Form”
- Recommended not to exceed two pages
- Include:
  - Data type
  - Related tools, software, and/or code
  - Standards
  - Data preservation, access, and associated timelines
  - Access, distribution, or reuse considerations
  - Oversight of data management and sharing
- Include costs in budget and justify in “Section L. Budget Justification” in “R&R Budget Form”
- Budget considered by reviewers & plan reviewed by NIH program staff
- Adjustments made through Just-in-Time (JIT) process
- Becomes part of Terms & Conditions of award
- Go to [sharing.nih.gov](https://sharing.nih.gov) for more information & examples



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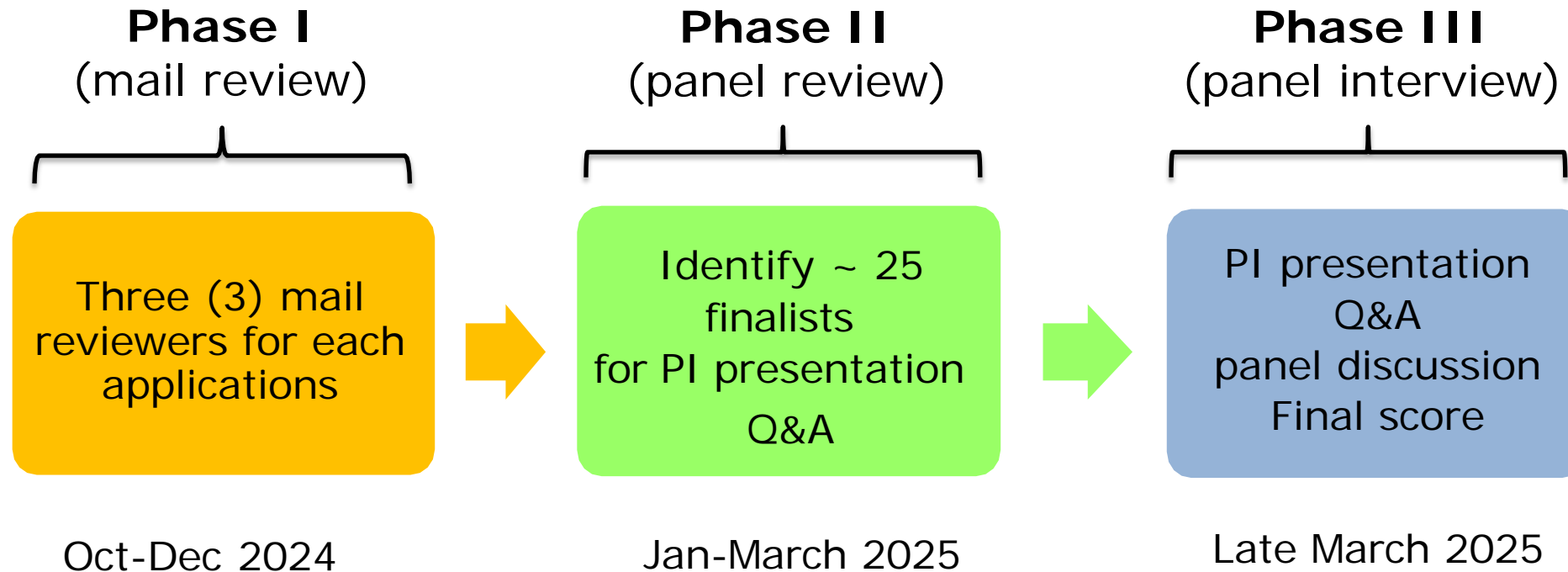
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# Pioneer Review Information

[RFA-RM-24-002](#)

(FY2025)

# Overview of Pioneer Review Process





# Broad Scientific Areas

Declare primary (**required**) secondary (optional) scientific areas

- In SF424 (R&R) Form, agency routing number (4b)
- In research strategy section

- 
1. Behavioral and Social Science (BSS)
  2. Chemical Biology (CB)
  3. Clinical and Translational Research (CTR)
  4. Infectious Diseases and Immunology (IDI)
  5. Instrumentation and Engineering (IE)
  6. Molecular and Cellular Biology (MCB)
  7. Neuroscience (NS)
  8. High-Throughput and Integrative Biology (HIB)
  9. Bioinformatics and Computational Biology (BCB)



# Mail Review

- All Pioneer (DP1) apps will be reviewed in one special panel
- Mail reviewers in 9 broad scientific areas/topics will be recruited
- Each application is assigned to 3 mail reviewers
  - 2 reviewers have expertise in the declared 'primary' scientific area
  - 1 reviewer has expertise in the declared 'secondary' scientific area
- Focus on specific Pioneer review criteria
  - The significance and innovation
  - The investigator's track record of conducting highly innovative research
  - A substantial change in research direction motivated by a fundamental new insight





# Panel Review

- A group of scientists with diverse scientific background and known for their broad scientific perspective will conduct the Phase II & III review
- Informed by phase I mail review inputs, the panel selects ~25 finalists that they deem to be the most “pioneering” for a presentation and panel discussion in late March 2025
- Finalist notification will be sent out in early March 2025

# Final Interview Consideration



- Is the Principal Investigator an individual with a track record of exceptional scientific creativity?
- Does the proposed project have the potential for broad impact?
- Does the proposal represent substantially different scientific directions from those already being pursued in the investigator's research program or elsewhere?
- Emphasis will be on “investigator” and “highly innovative project” for potential broad impact and suitability for the Pioneer Award
- **NOT** for a logical extension of project(s) that are likely supported by conventional NIH funding mechanisms

# Regular R01 vs Pioneer Review



Regular R01	Pioneer Award
One phase review process	<ul style="list-style-type: none"> <li>• Two (2) phase review (mail &amp; panel)</li> <li>• Finalists: PI presentation</li> </ul>
Subject matter experts	<ul style="list-style-type: none"> <li>• Mail review: broadly matched expertise vs scientific area</li> <li>• Panel review: <b>not</b> assigned by specific topic expertise</li> </ul>
Review criteria <ul style="list-style-type: none"> <li>• Significance/Impact</li> <li>• Investigator</li> <li>• Innovation</li> <li>• Approach</li> <li>• Environment</li> </ul>	Review criteria <ul style="list-style-type: none"> <li>• Significance/Innovation</li> <li>• Investigator's Innovative track record</li> <li>• Substantial new research direction</li> </ul>
Focus tends to be on approach and feasibility	Focus on investigator & innovation

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*Eligibility*

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*Application & Submission*

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*Budget*

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*Letters of Reference*

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*Review*

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