

This webinar is being recorded.

# Q&A Webinar

June 20, 2023 @ 3:00 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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[PioneerAwards@mail.nih.gov](mailto:PioneerAwards@mail.nih.gov)

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- 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

Ellie Murcia, M.Ed.

Program Specialist  
Office of the Director

# Common Fund Programs

- 4D Nucleome (4DN)
- Acute to Chronic Pain Signatures (A2CPS)
- Bridge to Artificial Intelligence (Bridge2AI)
- Cellular Senescence Network (SenNet)
- Community Partnerships to Advance Science for Society (ComPASS)
- Enhancing the Diversity of the NIH-Funded Workforce (DPC/BUILD)
- Extracellular RNA Communication (exRNA)
- Faculty Institutional Recruitment for Sustainable Transformation (FIRST)
- Gabriella Miller Kids First
- Global Health
- Harnessing Data Science for Health Discovery and Innovation in Africa (DS-I Africa)
- HCS Research Collaboratory
- High-Risk, High-Reward Research Program
  - Pioneer Award
  - New Innovator Award
  - Transformative Research Award
  - Early Independence Award
- Human BioMolecular Atlas Program (HuBMAP)
- Human Virome Program
- Illuminating the Druggable Genome (IDG)
- Metabolomics
- Molecular Transducers of Physical Activity Consortium (MoTrPAC)
- *Nutrition for Precision Health*, powered by *All of Us* Research Program
- Somatic Cell Genome Editing (SCGE)
- Somatic Mosaicism Across Human Tissues (SMAHT)
- Stimulating Peripheral Activity to Relieve Conditions (SPARC)
- Transformative High Resolution Cryo-Electron Microscopy (CryoEM)
- Transformative Research to Address Health Disparities and Advance Health Equity
- Undiagnosed Diseases Network (UDN)

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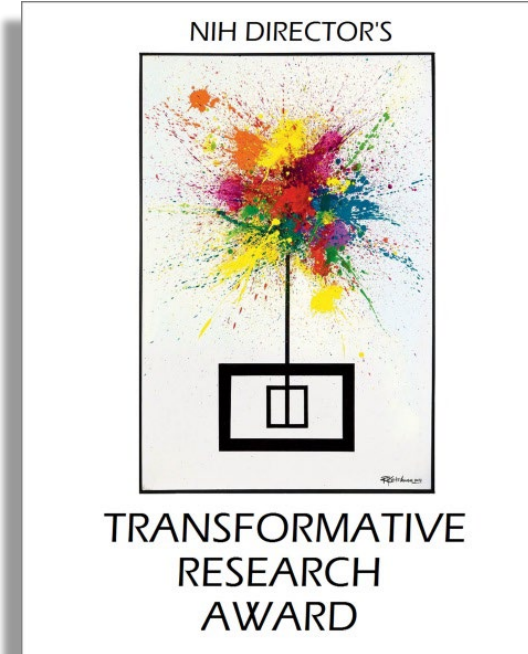
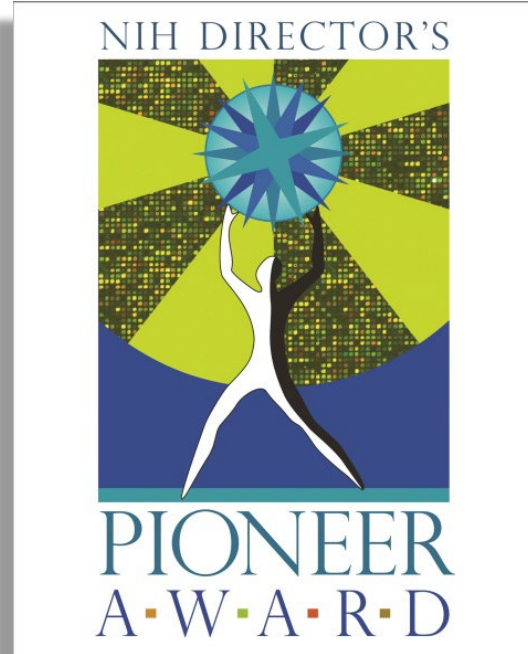
**CF programs may be useful for your research:  
funding opportunities, access to high-end  
instruments, databases, reagents, protocols, ....**

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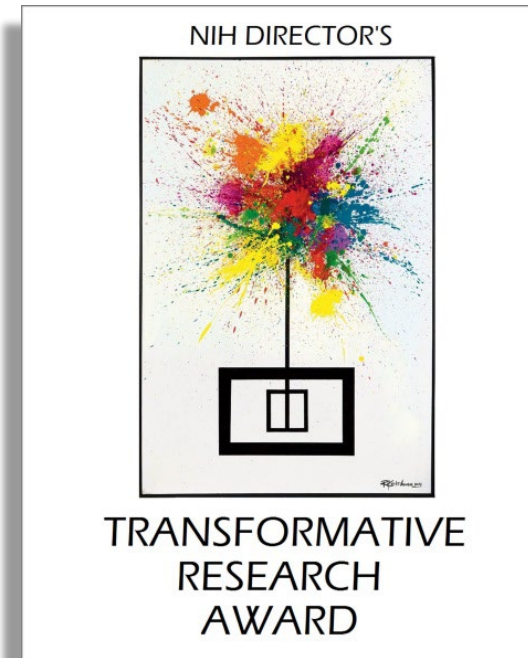
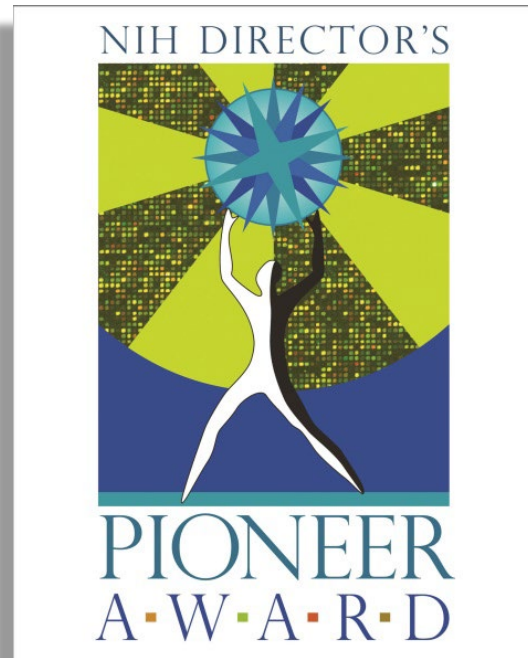


# High-Risk, High-Reward Research Program



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

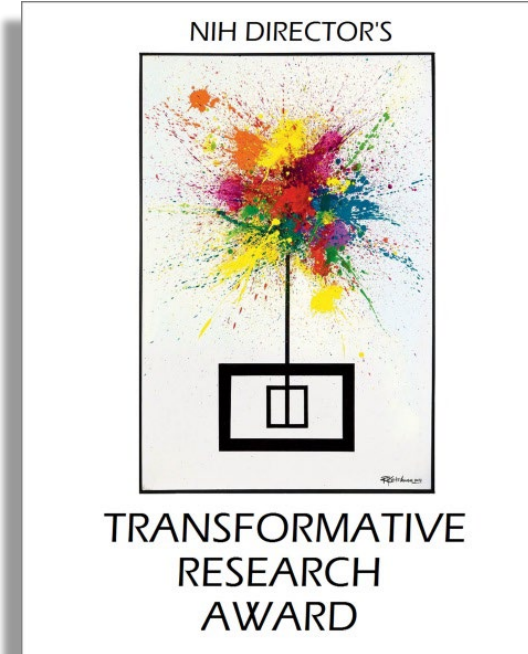
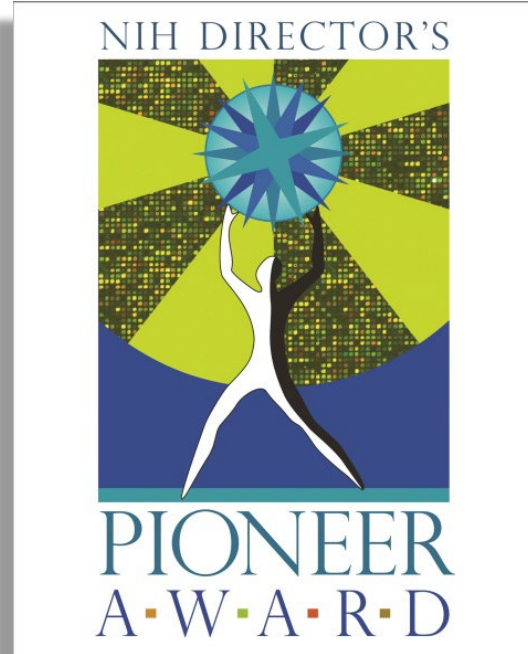
# High-Risk, High-Reward Research Program



Annual funding opportunities

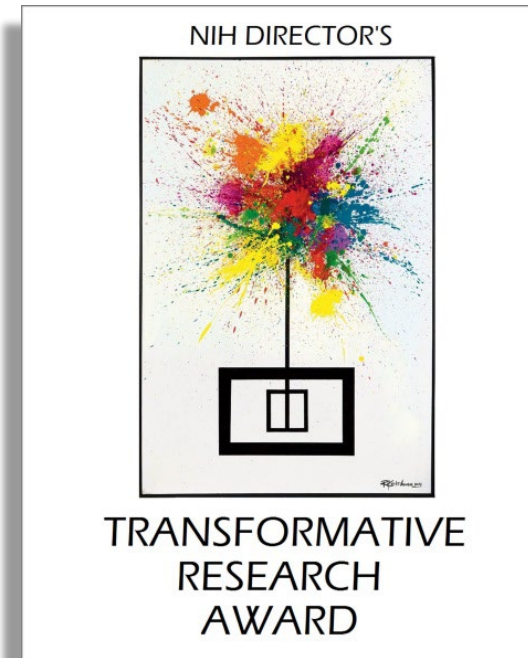
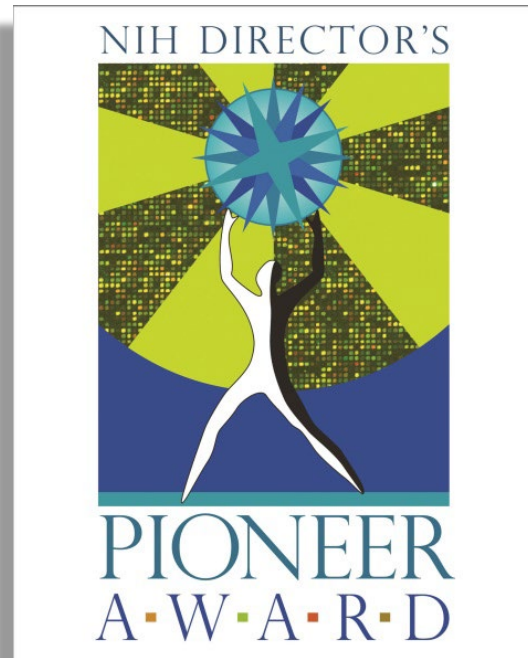


# High-Risk, High-Reward Research Program



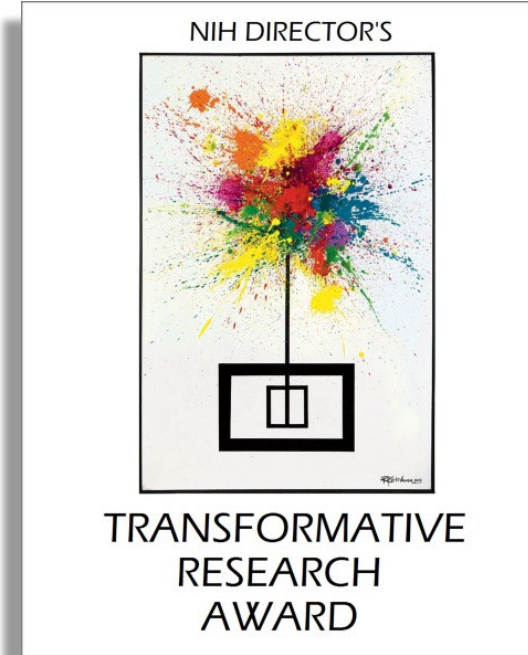
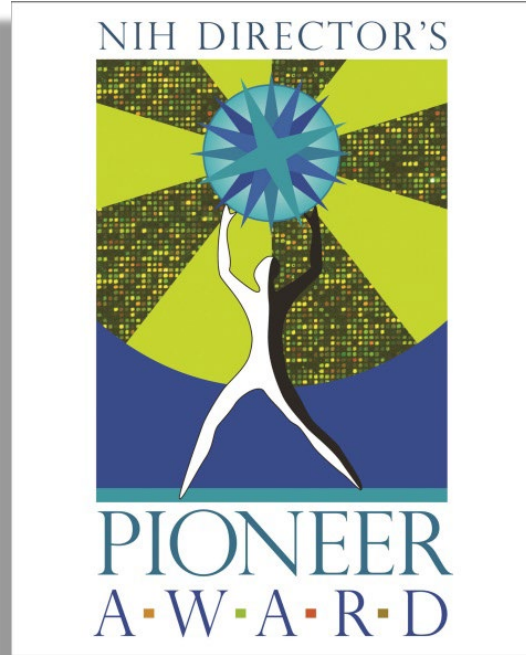
High-risk, high-impact ideas

# High-Risk, High-Reward Research Program



No preliminary data or detailed experimental plan required

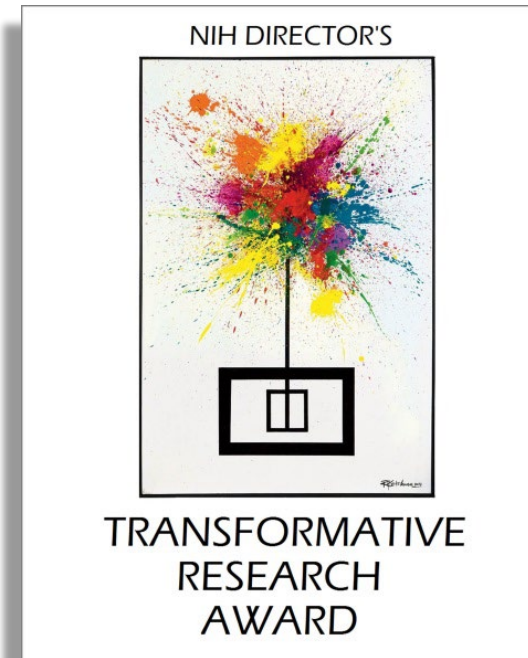
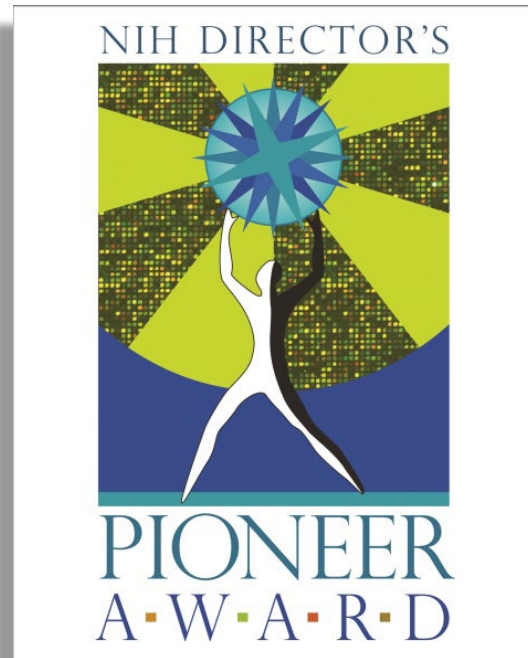
# High-Risk, High-Reward Research Program



*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**

Robert Eisinger (OD)

## **Program Leader**

Trish Labosky (OD)

## **Members**

Kristin Abraham (NIDDK)

Hugh Auchincloss (NIAID)

Geetha Bansal (FIC)

Alexey Belkin (NIAMS)

Sangeeta Bhargava (NEI)

Gene Carstea (CSR)

Jennifer Collins (NIEHS)

Christine Colvis (NCATS)

Bill Duval (NINR)

Emmeline Edwards (NCCIH)

Zeynep Erim (NIBIB)

Rene Etcheberrigaray (NIA)

Nancy Freeman (NIDCD)

Dana Greene-Schloesser (OD)

Gabriel Hidalgo (NIDCR)

Ray Jacobson (CSR)

Susan Koester (NIMH)

Trish Labosky (OD)

James Li (CSR)

Xinrui Li (CSR)

Roger Little (NIDA)

James Mack (CSR)

Becky Miller (OD)

Brett Miller (NICHD)

David Miller (NCI)

Michael Morse (OD)

Alok Mulky (CSR)

Ellie Murcia (OD)

Imoh Okon (CSR)

Richard Palmer (NLM)

Michael Pazin (NHGRI)

Steven Pittenger (NCATS)

Diana Rutberg (NIDCR)

Suzanne Ryan (CSR)

Michael Sakalian (NIGMS)

Sarita Sastry (CSR)

John Satterlee (NIDA)

Stefania Senger (CSR)

Doug Sheeley (OD)

Carol Shreffler (NIEHS)

Lillian Shum (NIDCR)

Barbara Sorkin (OD)

Cassandra Soto (CSR)

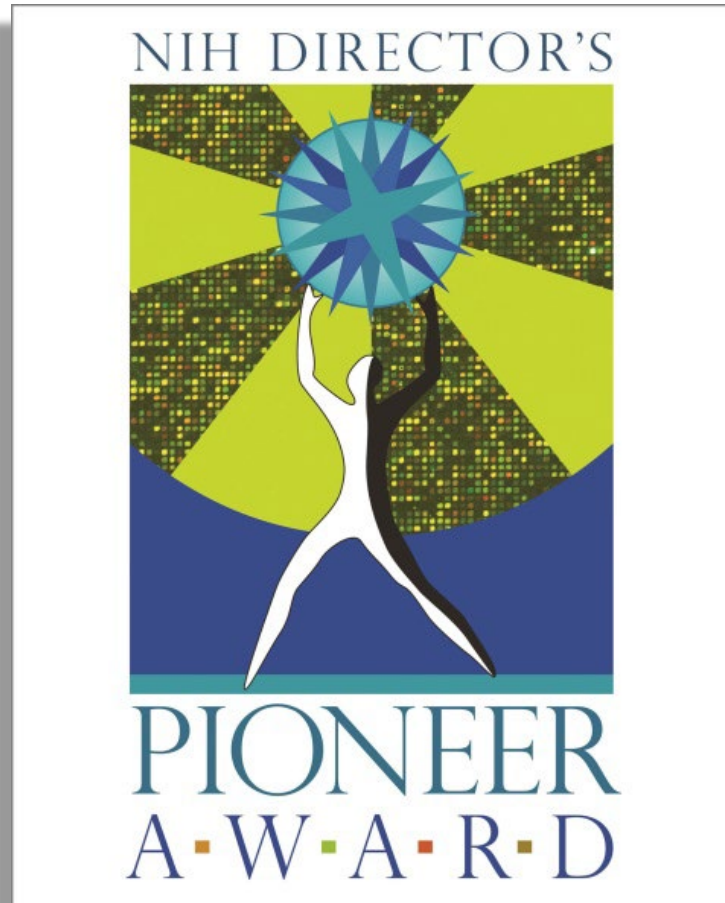
RV Srinivas (NIAAA)

Nathaniel Stinson (NIMHD)

William Tyler (NINDS)

Stephanie Webb (NHLBI)

# 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	3-5 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 experimental plan and extensive are 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)

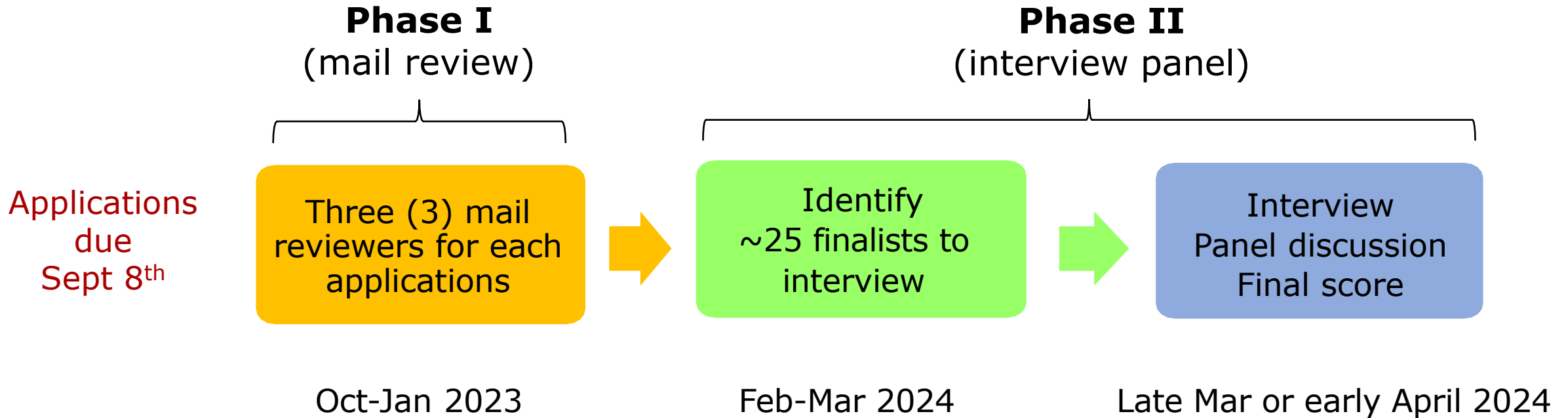
# Data Management & Sharing Plans

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"
- Not to exceed two pages in length
- Elements to 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
- Indicate costs as a line item in "Section F. Other Direct Costs" 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** for more information & examples



# Overview of Pioneer Review Process





# Broad Scientific Areas

Both Applicants and Mail Reviewers Declare  
Primary (**required**) secondary (optional)

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)

# Phase I Mail Review

- All Pioneer applications will be reviewed in one Special Emphasis Panel
- Mail reviewers in all scientific areas/topics will be recruited
- Each application is assigned to 3 mail reviewers
  - 2 reviewers have 'primary' expertise in the declared scientific area
  - 1 reviewer has 'secondary' expertise in the declared scientific area
- Focus on specific review criteria for Pioneer initiative
  - The significance and innovation
  - The investigator's track record of conducting highly innovative research
  - A change in research direction motivated by a fundamental new insight

# Phase II Interview Panel Review

- A group of scientists with diverse scientific background and known for their broad scientific perspective will conduct a second phase review
- Informed by phase I mail review inputs, Interview Panel selects ~25 applicants that they deem to be the most “pioneering” for an interview and discussion in late March/early April 2024

# 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 the extension of project(s) 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: interview</li> </ul>
Topic experts	<ul style="list-style-type: none"> <li>• Mail review: match broadly declared 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>• Innovation/impact</li> <li>• Investigator</li> <li>• 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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*Review*

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