

This webinar is being recorded.

Q&A Webinar

June 29, 2020 @ 3 PM EDT

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



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



TRANSFORMATIVE
RESEARCH
AWARD

<https://commonfund.nih.gov/tra>

Panelists

Ravi Basavappa, 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

Anthony Kirilusha, Ph.D.

Program Officer, National Institute of Arthritis and
Musculoskeletal and Skin Diseases
Member, HRHR Working Group

Ellie Murcia, M.Ed.

Program Specialist
Office of the Director

Amelie Gubitz, Ph.D.

Program Officer, National Institute of Neurological
Disorders and Stroke
Contact, ALS² Program

The Common Fund (in the NIH Office of the Director)

Current Programs:



The Common Fund

Data/Tools/Methods

- Big Data to Knowledge (BD2K)
- Gabriella Miller Kids First
- Genotype-Tissue Expression (GTEx)
- Glycoscience
- Human BioMolecular Atlas Program (HuBMAP)
- Illuminating the Druggable Genome (IDG)
- Knockout Mouse Phenotyping (KOMP)
- Library of Integrated Network-Based Cellular Signatures (LINCS)
- Metabolomics
- Regenerative Medicine Program (RMP)
- Science of Behavior Change (SOBS)
- Somatic Cell Genome Editing (SCGE)
- Stimulating Peripheral Activity to Relieve Conditions (SPARC)
- Transformative High Resolution Cryo-Electron Microscopy (CryoEM)

New Types of Clinical Partnerships

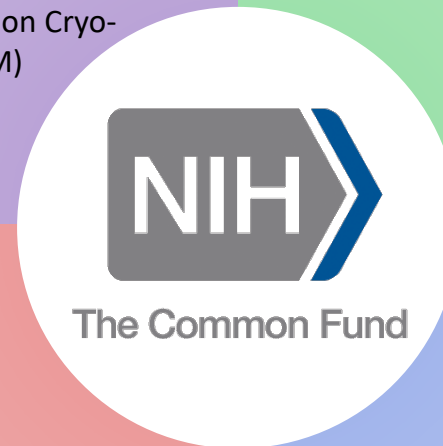
- Acute to Chronic Pain Signatures (A2CPS)
- Global Health
- HCS Research Collaboratory
- Undiagnosed Diseases Network (UDN)

New Paradigms

- 4D Nucleome (4DN)
- Extracellular RNA Communication (exRNA)
- Molecular Transducers of Physical Activity Consortium (MoTrPAC)

Transformative Workforce Support

- Enhancing the Diversity of the NIH-Funded Workforce (DPC/BUILD)
- High-Risk, High-Reward Research Program
 - Pioneer Award
 - New Innovator Award
 - Transformative Research Award
 - Early Independence Award
- Strengthening the Biomedical Research Workforce (BEST)



The Common Fund (in the NIH Office of the Director)

Current Programs:



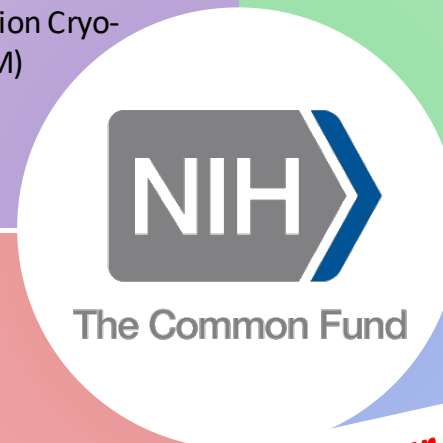
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New Paradigms

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- Molecular Transducers of Physical Activity

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

Translational Workforce Support

- Diversity of the NIH-Funded Workforce (DPC/BUILD)
- Research Career Development Award
- New Innovator Award
- Transformative Research Award
- Early Independence Award
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The Common Fund (in the NIH Office of the Director)

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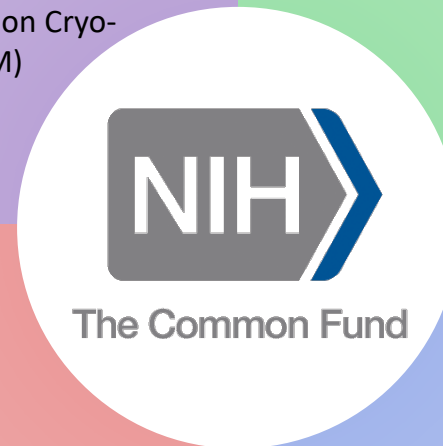
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Transformative Workforce Support

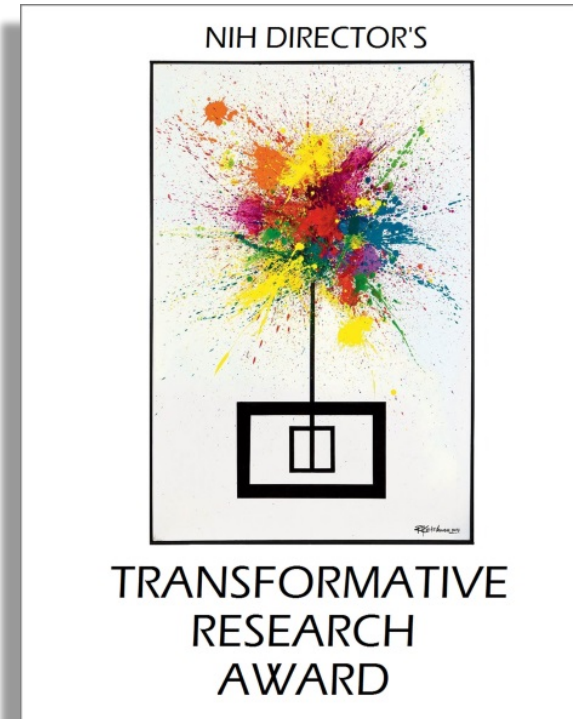
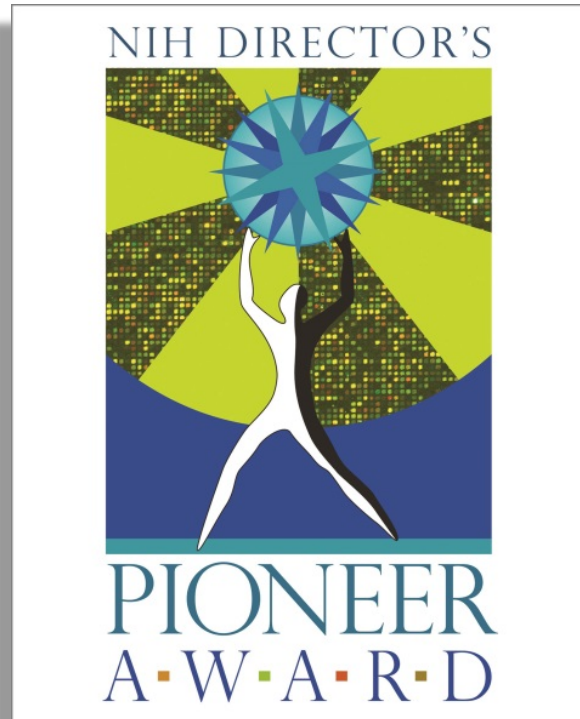
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High-Risk, High-Reward Research Program



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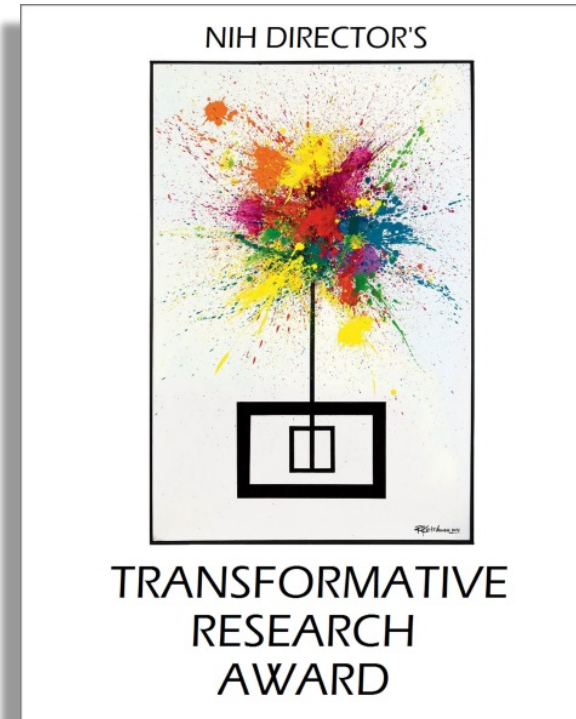
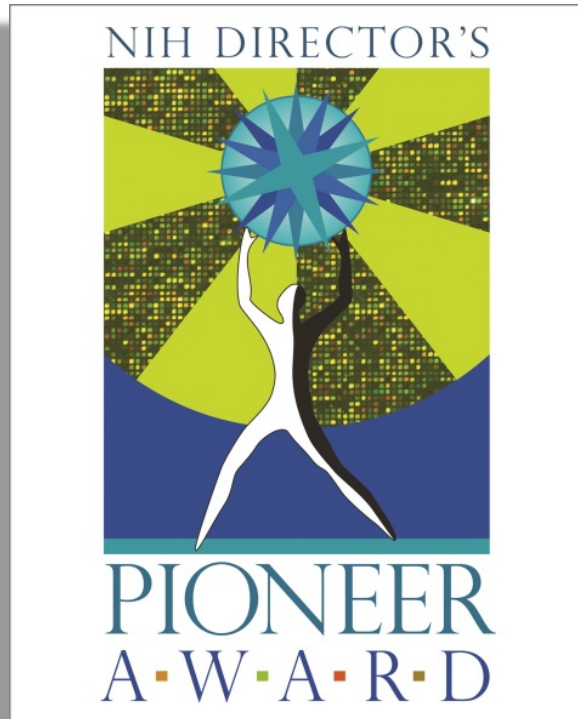


Annual funding opportunities

High-Risk, High-Reward Research Program



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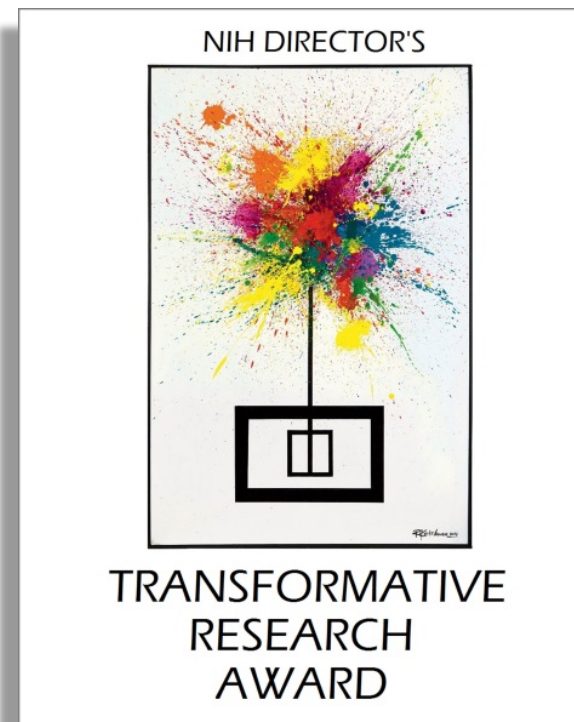
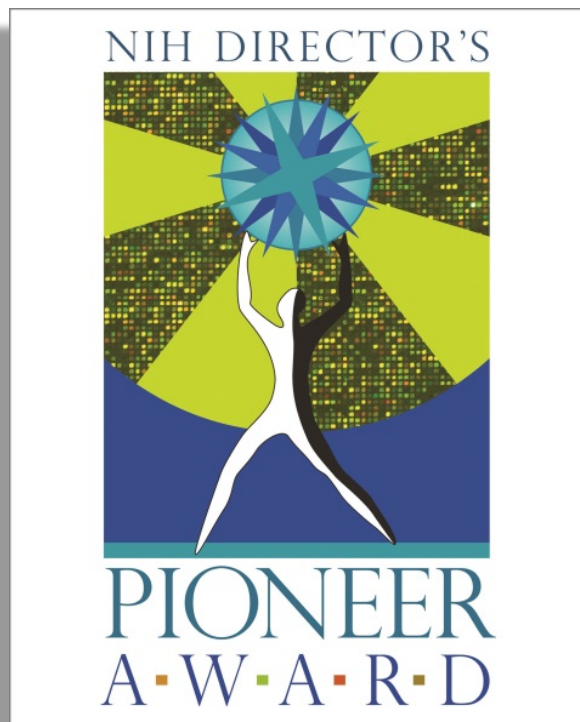


High-risk, high-impact ideas

High-Risk, High-Reward Research Program



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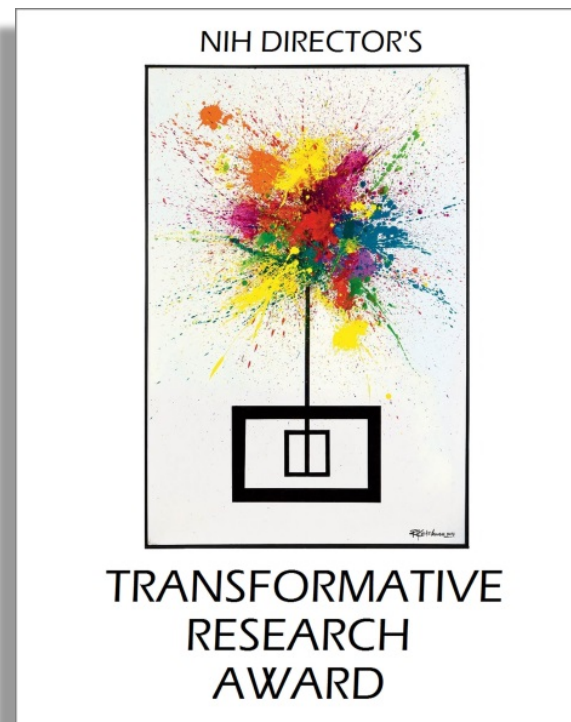
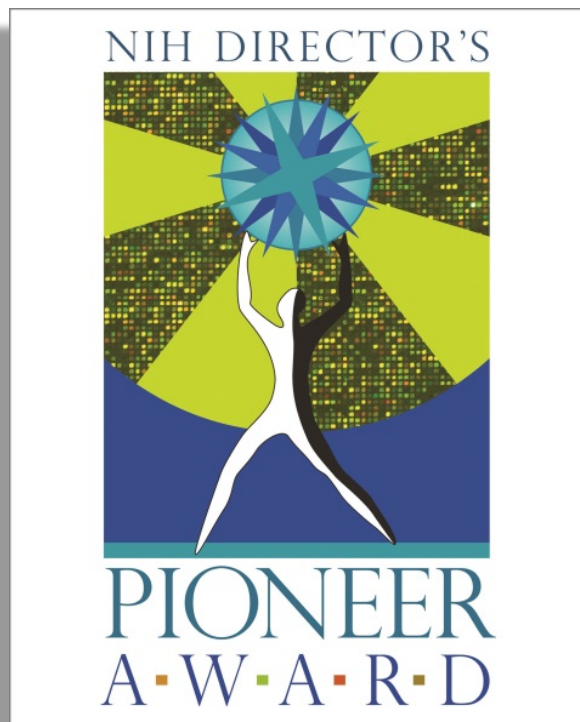


No preliminary data or detailed
experimental plan required

High-Risk, High-Reward Research Program



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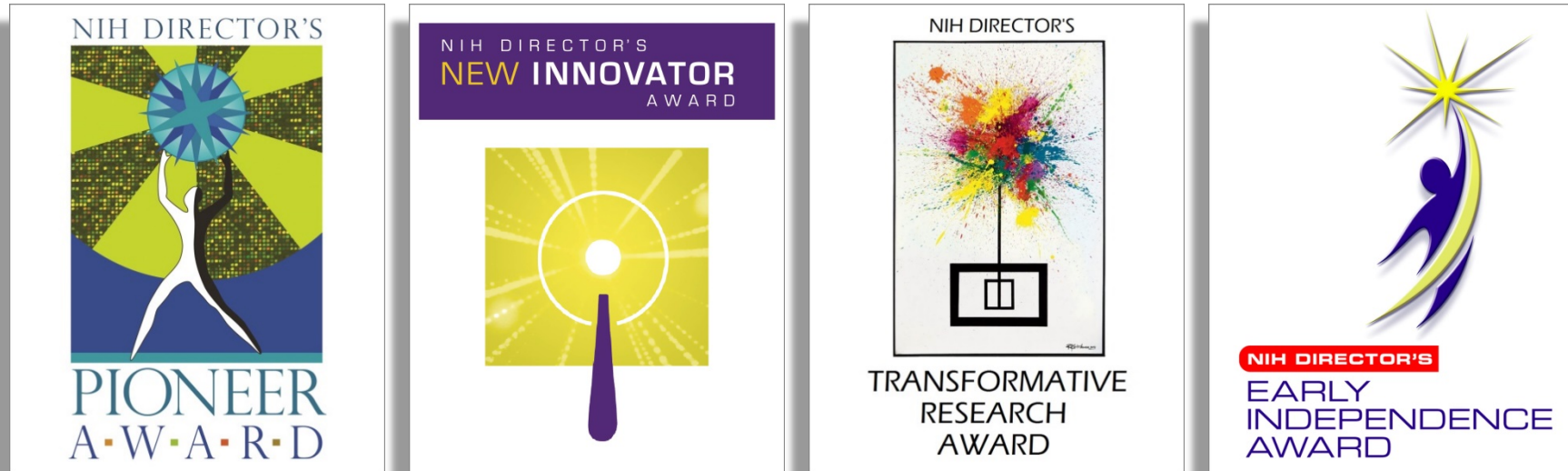


Any topic relevant to NIH mission

High-Risk, High-Reward Research Program



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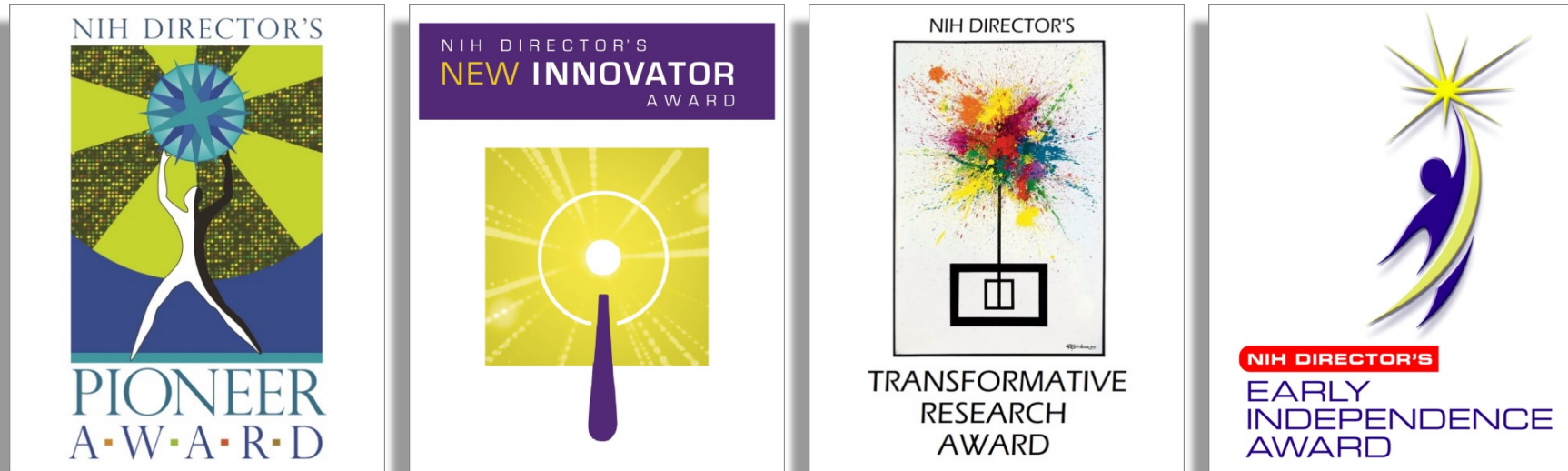


Any topic relevant to NIH mission, including:
behavioral, social, biomedical, applied, and formal sciences,
and basic, translational, or clinical research

High-Risk, High-Reward Research Program



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

High-Risk, High-Reward Research Program



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Chair

James M. Anderson, MD, PhD
OD

Program Leader

Ravi Basavappa, PhD
OSC/DPCPSI/OD

Members

Kristin Abraham, PhD
NIDDK

Vernon Anderson, PhD
NIGMS

Hugh Auchincloss, MD
NIAID

David Balshaw, PhD
NIEHS

Abraham P. Bautista, PhD
NIAAA

Eugene Carstea, PhD
CSR

Robert H Carter, MD
NIAMS

Jennifer Collins, MR
NIEHS

Christine Colvis, PhD
NCATS

Judith A. Cooper, PhD
NIDCD

**Milton Corn, MD, FACP,
FACMI**
NLM

Cindy D. Davis, PhD
Office of Dietary
Supplements/DPCPSI/OD

Emmeline Edwards, PhD
NCCIH

Zeynep Erim, PhD
NIBIB

Rene Etcheberrigaray, MD
NIA

Valerie Florance, PhD
NLM

Gabriel Hidalgo
NIDCR

Christine Hunter, PhD, ABPP
OBSSR/DPCPSI/OD

Raymond Jacobson, PhD
CSR

Flora Katz, PhD
FIC

Karen Kellton
OSC/DPCPSI/OD

Anthony Kirilusha, PhD
NIAMS

Susan Koester, PhD
NIMH

Rajiv Kumar, PhD
CSR

James Li, PhD
CSR

Roger Little, PhD
NIDA

James Mack, PhD
CSR

Judy A. Mietz, PhD
NCI

Becky Miller, PhD
OSC/DPCPSI/OD

Brett Miller, PhD
NICHD

Daniel Miller, PhD
NINDS

Michael Morse
OSC/DPCPSI/OD

Ellie Murcia, MEd
OSC/DPCPSI/OD

Srikanth Ranganathan, PhD
CSR

Diana (Dede) Rutberg, MBA
NIDCR

Suzanne Ryan, PhD
CSR

John Satterlee, PhD
NIDA

Carol Shreffler, PhD
NIEHS

Lillian Shum, PhD
NIDCR

Darren Sledjeski, PhD
NIDCR

Heidi J. Sofia, PhD
NHGRI

Michael A. Steinmetz, PhD
NEI

**Nathaniel Stinson, Jr., PhD,
MD**
NIMHD

Edmund Talley, PhD
NINDS

**Stephanie Johnson Webb,
PhD**
NHLBI

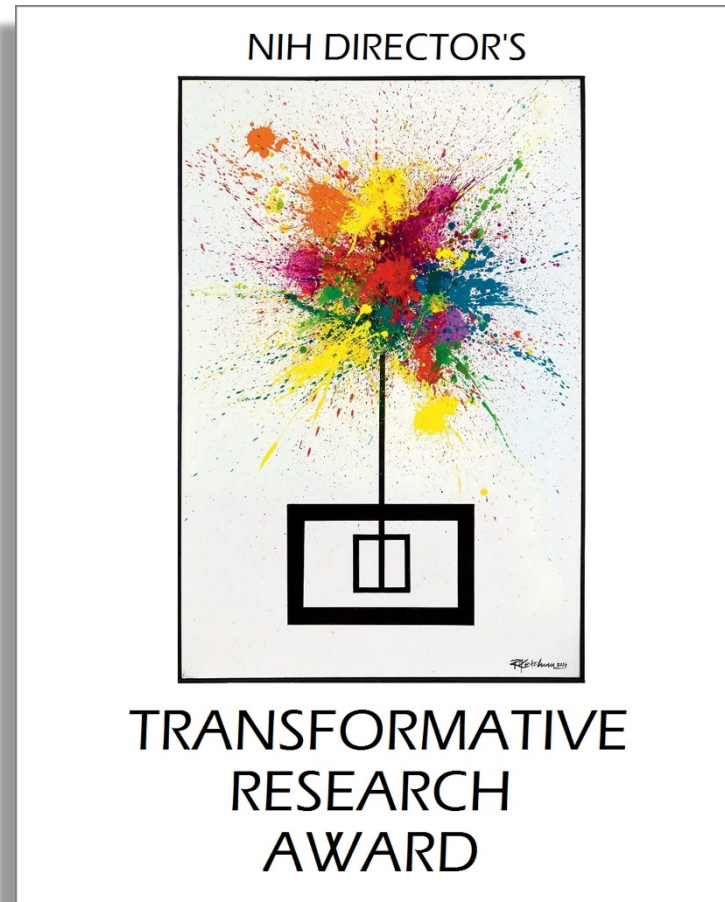
Tasmeen Weik, DrPH, MPH
CSR

Elizabeth L. Wilder, PhD
OSC/DPCPSI/OD

Transformative Research Award (TRA)



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Supports exceptionally innovative or unconventional research projects with the potential to create or overturn fundamental paradigms

- Started in 2009
- Open to individuals or teams at all career stages
- No preliminary data required
- Flexible budgets
- No prior approval required for large budget requests
- Cannot be renewed

Advisory Committee to the Director Report



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The Advisory Committee to the Director evaluated the HRHR program, issued report in June 2019 (<https://www.acd.od.nih.gov/working-groups/hrhr.html>)

- Found that the HRHR program is effective in supporting unusually innovative and impactful research
- Underrepresented groups overall not adversely affected by review process
- More fundamental concern is that underrepresented groups do not apply at rate that reflects their composition in the workforce
- Awards tend to go to a subset of institutions
- One recommendation is to pilot anonymized review
- Will be piloting anonymized review for TRA this year

Uses R01 application, but in an unconventional way

Specific Aims page	<ul style="list-style-type: none">• Not used to list specific objectives of project as in standard R01 application• Instead, used as a one-page distillation of project and why it is well-aligned with the spirit of the TRA initiative• Two sections:<ul style="list-style-type: none">○ Significance, Innovation, Impact○ Insight and rationale
Research Strategy section	<ul style="list-style-type: none">• Not used as in standard R01 application with substantial preliminary data and experimental details• Instead, used to address items of programmatic importance to TRA• Five sections:<ul style="list-style-type: none">○ Overview of research project (set context for project)○ Approach (describe underlying logic and will ensure robustness and rigor)○ Innovation (explain why exceptionally innovative)○ Appropriateness for TRA (explain why HRHR and not traditional R01)○ Timeline (including critical decision points)

Points to consider:

- Given that not all reviewers will be topic experts, 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
- 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 it is so innovative and potentially impactful
- Ease the reader into the jargon of the field
- Though no detailed experimental plan is required, make clear what it is that you want to do
- Convince the reviewers that you have thought deeply about the project – identify risky aspects, how they will be mitigated, alternate approaches
- Also, convince the reviewers 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)

TRA Anonymization of Application



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For anonymized review, the **Specific Aims page** and the 12-page **Research Strategy section** must not contain the following:

- Names of any individuals or institutions
- Mention of any honors or awards
- Hyperlinks
- Reference to any investigator attributes or accomplishments, such as “as leaders in this field” or “we have shown”
- Citations that provide specific information about the source. Use numeric citations only, which refer to the corresponding source in the “Bibliography & References Cited” component of the application
- Any other text from which the identity of any participating individual or institution can be reasonably inferred

Inclusion of any such information will result in application being administratively withdrawn.

(Write other application components using standard SF424 instructions.)

TRA - three “flavors” this year



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Standard (RFA RM20-013) – any topic of relevance to the NIH mission is welcome

COVID-19 – related (RFA RM20-020) – must be relevant to SARS-CoV-2 prevention, preparation, or response.

- Includes behavioral/social science research, research on health disparities, novel therapeutics, and any other related topics.
- As with standard TRA, innovation may be technical and/or conceptual, but **must** be at a very high level.

Amyotrophic lateral sclerosis (ALS)-related (NOSI RM20-019) – see next slides

All have the same receipt date (September 30, 2020) and all will use the anonymized review process with the same study section.

Accelerating Leading-edge Science in ALS (ALS²)



The Common Fund

- ❖ Companion program focused on Amyotrophic Lateral Sclerosis (ALS) to the NIH Director's Transformative Research Award program
- ❖ Seeks to spur innovative research on ALS, a progressive and fatal neurological disease that weakens and eventually paralyzes voluntary muscles
- ❖ Notice of Special Interest (NOSI): Common Fund ALS-related Transformative Research Award (R01 Clinical Trial Optional)
- ❖ Notice Number: NOT-RM-20-019

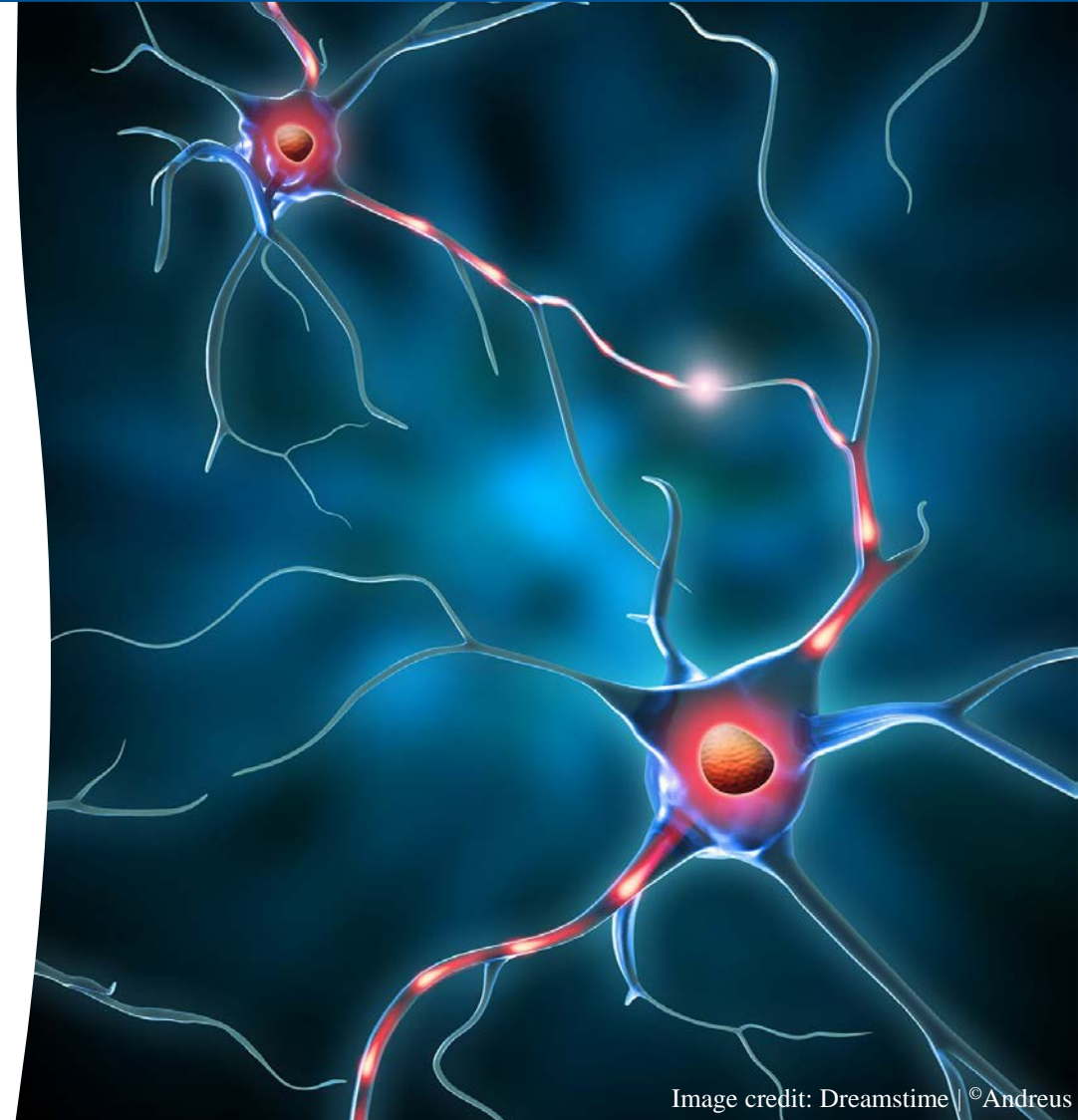


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Accelerating Leading-edge Science in ALS (ALS²)



The Common Fund

The following elements are encouraged:

- ❖ Adapt emerging tools and technologies from neuroscience, cell biology and other disciplines to identify what causes ALS and how the disease progresses, forming the basis for new potential therapeutic strategies.
- ❖ Attract new talent from a range of scientific disciplines, including cell biology, bioengineering, chemistry, biophysics, environmental health sciences, and computational science, and initiate new interdisciplinary collaborations.
- ❖ Examine biological similarities between ALS and motor neuron disease in other neurodegenerative disorders

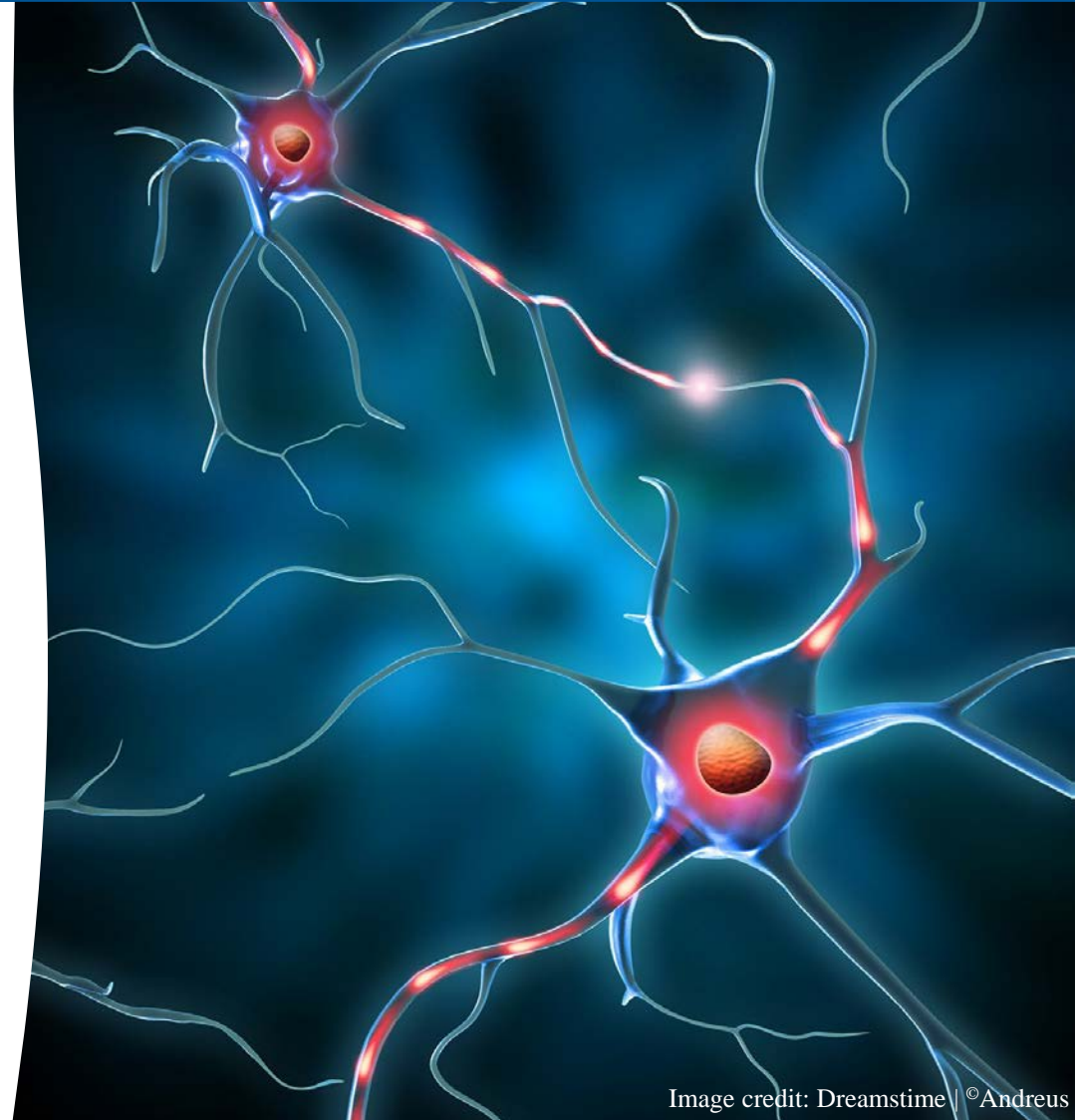


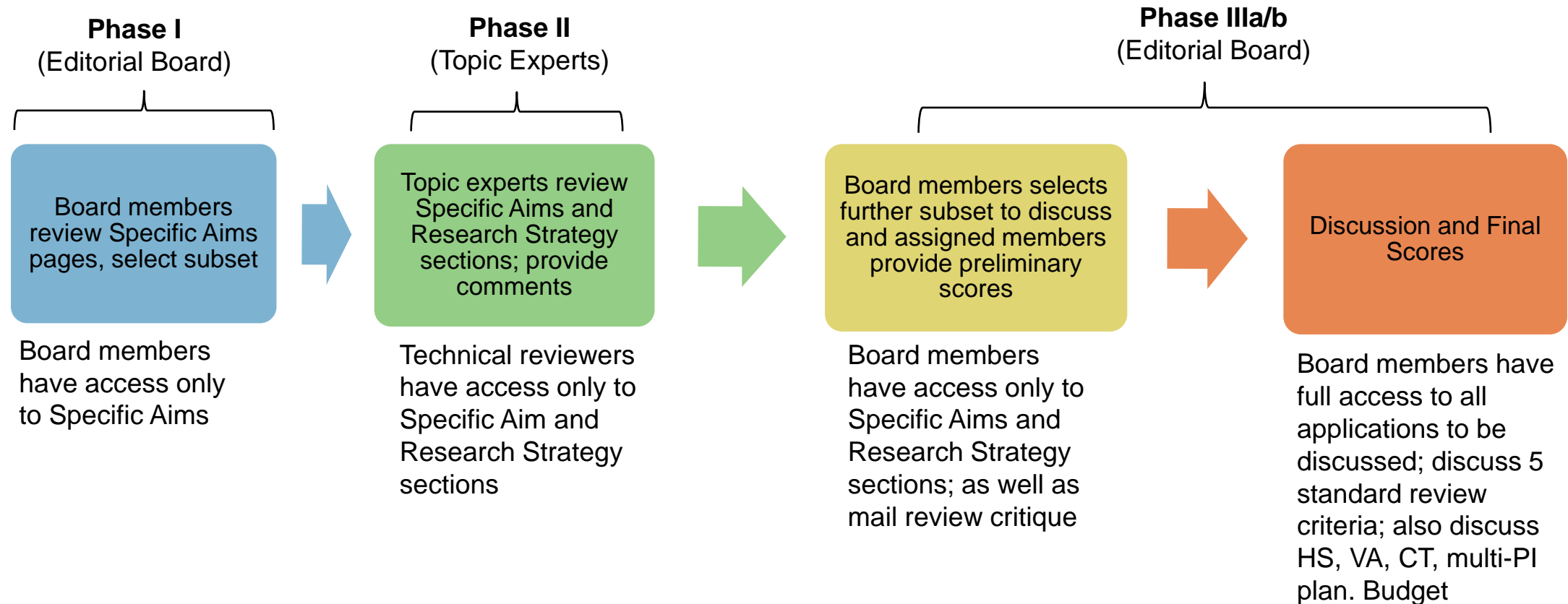
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CSR Review Process for the NIH Director's Transformative Research Awards

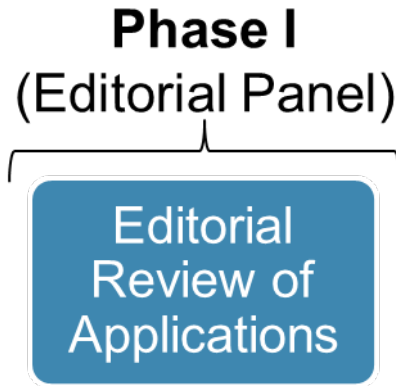
James Li, Ph.D.
Scientific Review Officer
NIH Center for Scientific Review
lijames@csr.nih.gov

Overall Transformative Research Award Review Process



- Both Specific Aims page & Research Strategy section are anonymized
- Review phase I, II, IIIa (**anonymized**); phase IIIb (full access of application)

Phase I: Editorial Review of Applications

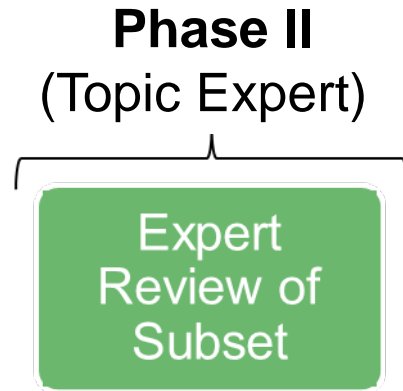


Timeline:

- NIH Admin Review (anonymization): early - mid October
- Phase I Review: late October to mid-December
- Number of Applications: 150 - 200

- The editorial board review panel is composed of 16-20 high-level, senior scientists with collective expertise spanning from diverse scientific areas that broadly cover the NIH research portfolio
- Each editor reviews ~ 50 randomly assigned applications based on **anonymized** Specific Aims page during Phase I; and places them in bins reflecting editor's assessment of the potential transformative impact
- Each application is reviewed by 4 editors
- Top scoring subset of applications plus any selected for rescue by any of the editors advance to Phase II

Phase II: Technical Review of Applications

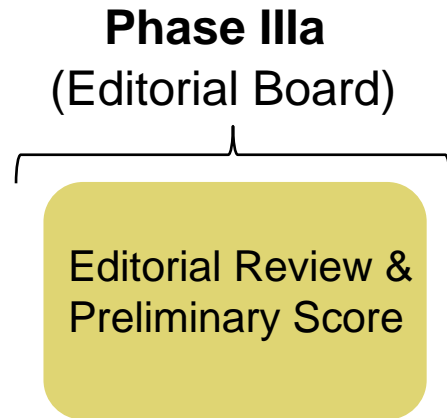


Timeline:

- Phase II Review: January to end February 2021
- Number of Applications: 70-80

- The top (70-80) applications selected by the Editorial Board members from Phase I are distributed to various IRGs that cover the area of science contained within each application
- For each application, 3 topic experts are recruited as mail reviewers who have access only to the **anonymized** Specific Aim page and Research Strategy section.
- The mail reviewers provide written comments addressing significance and transformative impact, the level of innovation, and the logic of approach. No scores are provided.

Phase IIIa: Editorial Review and Preliminary Score



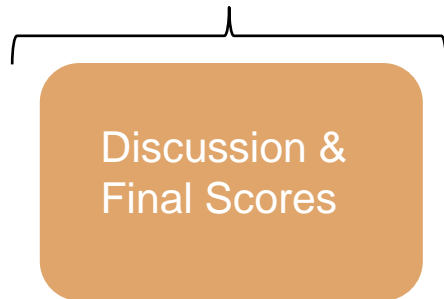
Timeline:

- **Phase IIIa: early to end March 2021**
- **Number of Applications: 70-80**

- All editors have access to **anonymized** Specific Aims page & Research Strategy section as well as the corresponding mail reviews from Phase II
- Each editor is randomly assigned ~ 20 applications; review and provide preliminary scores taking into account both their own assessment and input from mail reviews.
- Generally, the top half of the applications from the Phase II set, plus any selected for rescue are brought up for discussion in Phase IIIb in early April

Phase IIIb: Review Discussion and Final Score

Phase IIIb (Editorial Board)



Timeline:

- Phase IIIb: early April 2021
- Number of Applications: TBD

- All editors now have **full access** to the complete applications, will consider the 5 standard criteria including investigator and environment as well as HS, CT, VA and multi-PI plan for final review discussion.
- The editors provide the final Overall Impact scores after the discussion taking into account both their own assessment of entire application, and input from panel discussion and the mail review.

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Eligibility



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Application & Submission



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Budget



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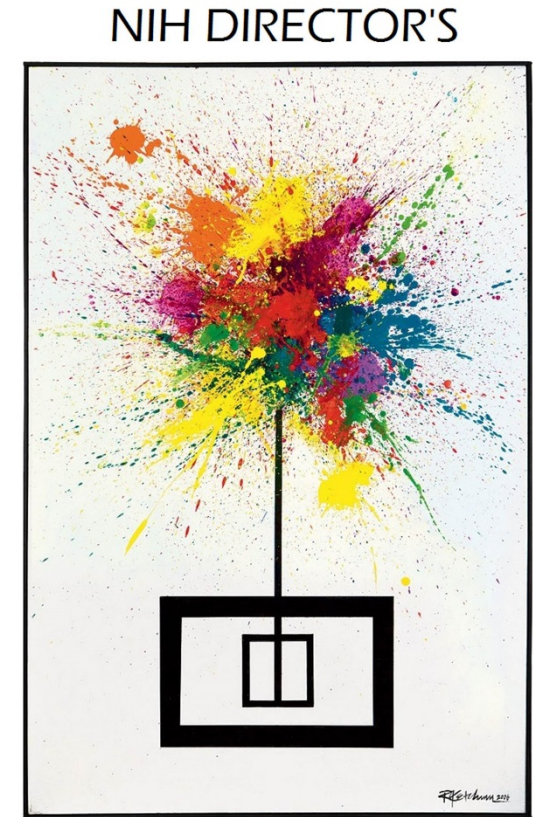
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Review



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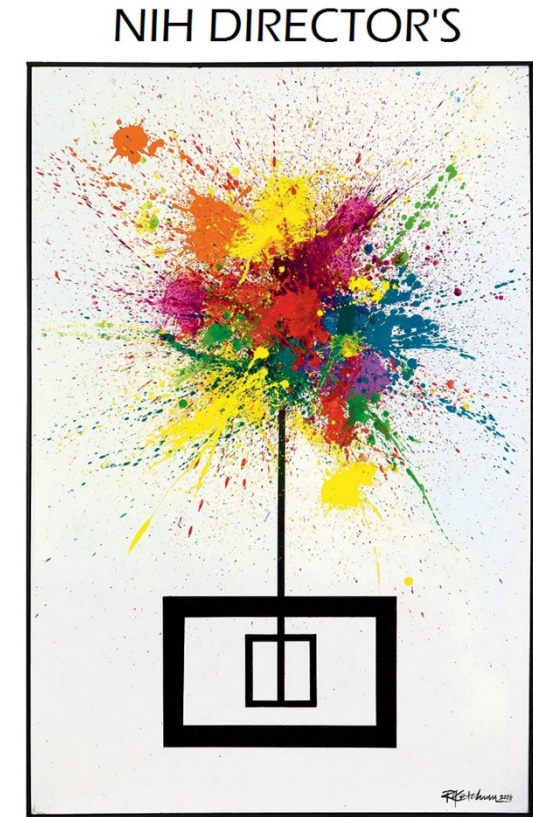
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Video: commonfund.nih.gov/tra



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