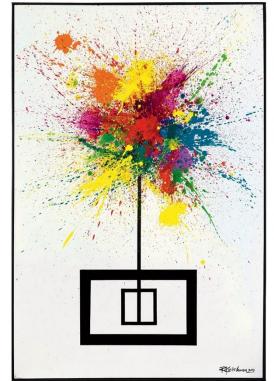
Q&A Webinar

June 29, 2021 @ 1:00 PM EDT

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





TRANSFORMATIVE RESEARCH AWARD

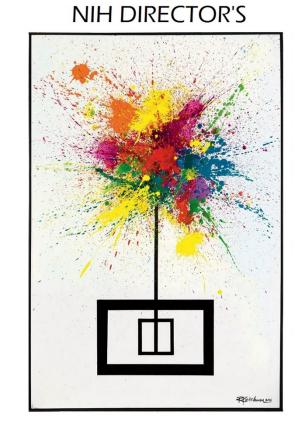
commonfund.nih.gov/tra Transformative_Awards@mail.nih.gov



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

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 <u>Transformative_Awards@mail.nih.gov</u>
- Webinar recording & slides will be posted on website at <u>commonfund.nih.gov/tra</u>
- For more application guidance, see our <u>Application</u> <u>& Award Guide</u> on website (includes example applications)



TRANSFORMATIVE RESEARCH AWARD



commonfund.nih.gov/tra

Panelists

Ravi Basavappa, Ph.D.

Program Leader Office of the Director

Becky Miller, Ph.D.

Program Officer Office of the Director

Makyba Charles-Ayinde, Ph.D.

Health Science Policy Analyst Office of the Director

Ellie Murcia, M.Ed.

Program Specialist Office of the Director

James Li, Ph.D.

Scientific Review Officer Center for Scientific Review

The Common Fund (in the NIH Office of the Director) Current Programs:



Data/Tools/Methods

- Bridge to Artificial Intelligence (Bridge2AI)
- Cellular Senescence Network (SenNet)
- Gabriella Miller Kids First
- Genotype-Tissue Expression (GTEx)
- Glycoscience
- Human BioMolecular Atlas Program (HuBMAP)
- Illuminating the Druggable Genome (IDG)
- Knockout Mouse Phenotyping (KOMP)
- Metabolomics

New Paradigms

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

- Protein Capture Reagents
- Library of Integrated Network-Based Cellular Signatures (LINCS)
- Science of Behavior Change (SOBC)
- Somatic Cell Genome Editing (SCGE)
- Stimulating Peripheral Activity to Relieve Conditions (SPARC)
- Transformative High Resolution Cryo-Electron Microscopy (CryoEM)



The Common Fund

New Types of Clinical Partnerships

- Acute to Chronic Pain Signatures (A2CPS)
- Global Health
- Harnessing Data Science for Health Discovery and Innovation in Africa (DS-I Africa)
- HCS Research Collaboratory
- Nutrition for Precision Health, powered by the All of Us Research program
- Undiagnosed Diseases Network (UDN)

Transformative Workforce Support

- Enhancing the Diversity of the NIH-Funded Workforce (DPC/BUILD)
- Faculty Institutional Recruitment for Sustainable Transformation (FIRST)
- High-Risk, High-Reward Research Program
 - Pioneer Award
 - New Innovator Award
 - Transformative Research Award
 - Early Independence Award
- Transformative Research to Address Health Disparities and Advance Health Equity

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New Paradigms

- 4D Nucleome (4DN)
- Extracellular RNA Communication (exRNA)
- CF programs may be useful for your research: FOAs, access to high-end instruments, databases, Molecular Transducers of Physical Activity Consortium (MoTrPAC)

- Protein Capture Reagents
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Annual funding opportunities



High-risk, high-impact ideas



No preliminary data or detailed experimental plan required



Any topic relevant to NIH mission

High-Risk, High-Reward Research Program





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





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

High-Risk, High-Reward Research Program



The Common Fund

<u>Chair</u>

James M. Anderson, MD, PhD NCATS OD Milton

Program Leader

Ravi Basavappa, PhD OSC/DPCPSI/OD

<u>Members</u>

Kristin Abraham, PhD NIDDK

Hugh Auchincloss, MD NIAID

David Balshaw, PhD NIEHS

Abraham P. Bautista, PhD NIAAA

Eugene Carstea, PhD CSR

Robert H Carter, MD NIAMS

Makyba Charles-Ayinde, PhD OBSSR/DPCPSI/OD OSC/DPCPSI/OD Raymond Jacobsor

Jennifer Collins, MR NIEHS **Christine Colvis, PhD** Milton Corn, MD, FACP, FACMI NLM **Emmeline Edwards, PhD** NCCIH Zeynep Erim, PhD NIBIB Rene Etcheberrigaray, MD NIA Lia Fleming, MPH **CSR** Valerie Florance, PhD NLM Nancy Freeman, PhD NIDCR **Gabriel Hidalgo** NIDCR Christine Hunter, PhD, ABPP **Raymond Jacobson, PhD**

CSR

Flora Katz, PhD FIC Anthony Kirilusha, PhD NIAMS Susan Koester. PhD NIMH 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

David Miller, PhD NCI

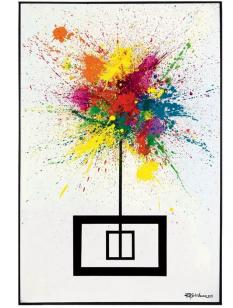
Michael Morse OSC/DPCPSI/OD Ellie Murcia, MEd OSC/DPCPSI/OD Imoh Okon, PhD CSR **Steven Pittenger** NCATS Srikanth Ranganathan, PhD CSR Diana (Dede) Rutberg, MBA NIDCR Suzanne Ryan, PhD CSR John Satterlee. PhD NIDA **Carol Shreffler, PhD** NIEHS

Lillian Shum, PhD NIDCR

Darren Sledjeski, PhD NIGMS Heidi J. Sofia, PhD NHGRI **Barbara Sorkin** ODS/DPCPSI/OD Michael A. Steinmetz. PhD NEL 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



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TRANSFORMATIVE RESEARCH AWARD 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



Uses R01 application, but in an unconventional way

Specific Aims page	 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: Significance, Innovation, Impact Insight and rationale
Research Strategy section	 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: 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)

Advisory Committee to the Director Report



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

- 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

TRA anonymized review pilot



- Intention of anonymized review pilot is to focus on the research idea, its innovativeness, and its
 potential impact.
- Investigator and environment criteria will be evaluated near the end of the multi-phase review process, but for most of the review, the identity of the participating investigator or institutions will not be known.
- Began pilot for FY2021 awards (receipt date in Sept. 2020).
- Results are encouraging:
 - o substantial fraction of applicants incentivized to apply because of anonymization
 - o overall, applicants were still to able to prepare applications that conveyed innovation and impact
 - \circ $\,$ reviewers were still able to evaluate innovation and impact with information at hand
- Pilot is continuing for a second of probably three years

TRA Anonymization of Application



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

Thus, the Specific Aims page must not include:

- Names of any individuals, whether participating or not in the proposed research
- Names of any institutions, whether participating or not in the proposed research, unless the named institution is in reference to a publicly available resource, such as a database or biobank
- Mention of any honors or awards, or other specific attributes of any participating investigator
- Hyperlinks
- Reference to any investigator accomplishments in the public domain (including in publications or available in preprint servers), such as "we developed this technology," "the PIs demonstrated that," "our team was the first to," or "our collaborators are pioneers in"
- 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.



Be sure to follow the anonymization instructions carefully!

Examine the Specific Aims and Research Strategy sections to make sure there are no violations of the text.

Better to try to comply with the spirit of anonymization than to try to game the system.

Complete all other components of the application following the SF424 application guide. **Other components do not need to be anonymized.**

Describe investigator suitability for the proposed research in the biosketch.

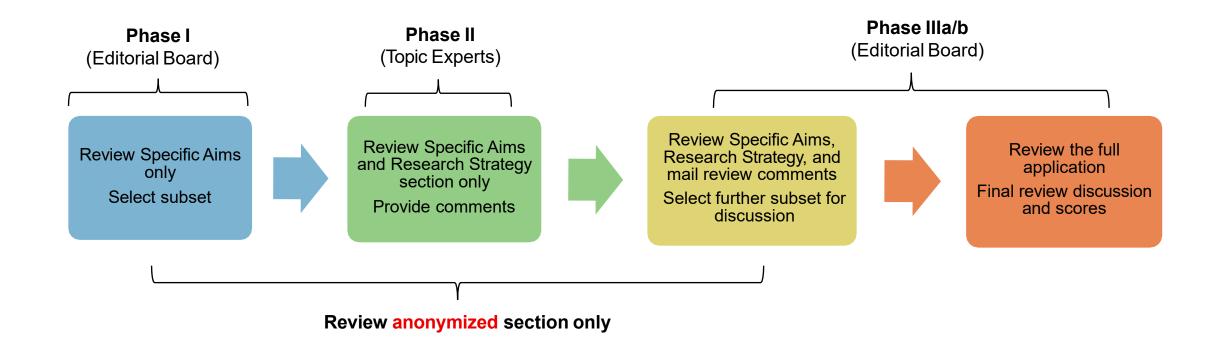


Review Process for the NIH Director's Transformative Research Awards (RFA-RM-21-017)

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

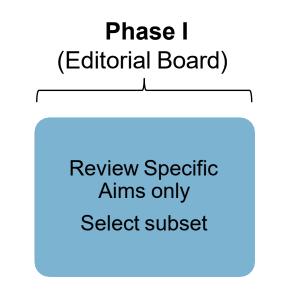


Overview of Multi-stage Editorial Board Review Process





Phase I: Editorial Review of Applications

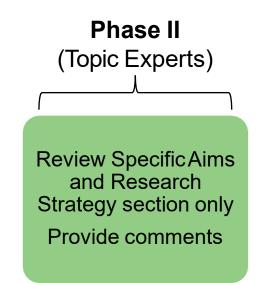


- NIH Admin Review (anonymization): early mid September
- > Phase I Review: late September to late November, 2021
- Number of Applications: 150 200

- The editorial board review panel is composed of 16-20 senior scientists with collective expertise spanning from diverse scientific areas that broadly cover the NIH research portfolio
- Each editor reviews 40-50 applications based on anonymized Specific Aims page during Phase I; and places them in bins reflecting their assessment of the potential transformative impact
- Each application is reviewed by 4 editors
- Top scoring subset of applications plus any rescues are advanced to Phase II



Phase II: Technical Review of Applications



- > Phase II Review: December to mid February 2022
- Number of Applications: 70-80

- The top (70-80) applications selected from Phase I are reviewed by mail reviewers who are topic experts in the area of science presented in each application
- Each application is reviewed by 3 topic experts 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 Illa: Editorial Review and Preliminary Score

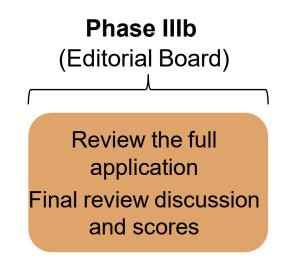


- > Phase IIIa: late February to late March 2022
- > Number of Applications: 70-80

- The editorial board review panel have access to anonymized Specific Aims page, Research Strategy section as well as the corresponding mail reviews from Phase II
- Each editor is assigned 15-20 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 rescues are brought up for final review discussion in Phase IIIb in early April



Phase IIIb: Review Discussion and Final Score



- > Phase IIIb: early April 2022
- > Number of Applications: TBD

- The editorial board review panel have **full access** to the complete applications, will consider the 5 standard criteria including investigator and environment as well as HS, 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 <u>entire</u> application, and input from panel discussion and the mail review.



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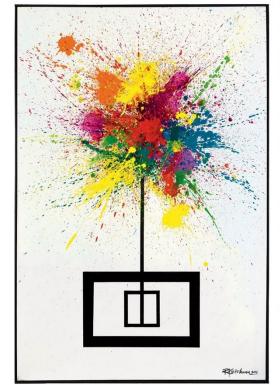
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Eligibility





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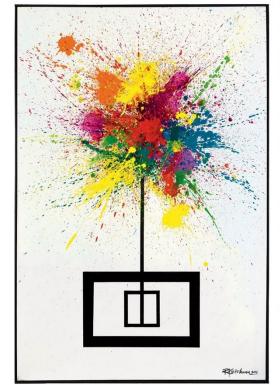
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Application & Submission



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TRANSFORMATIVE RESEARCH AWARD

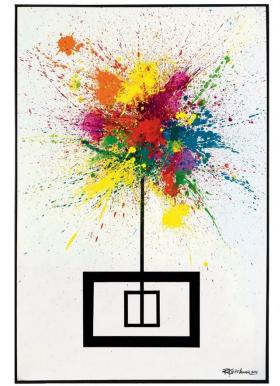
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Budget



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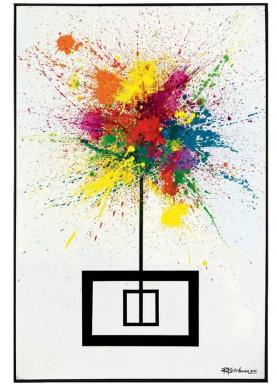
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Review



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Thank you for attending.

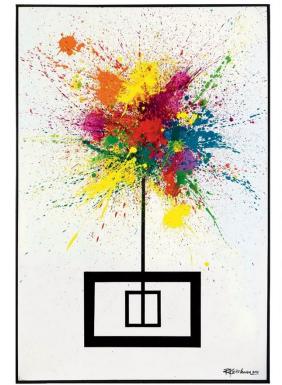
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