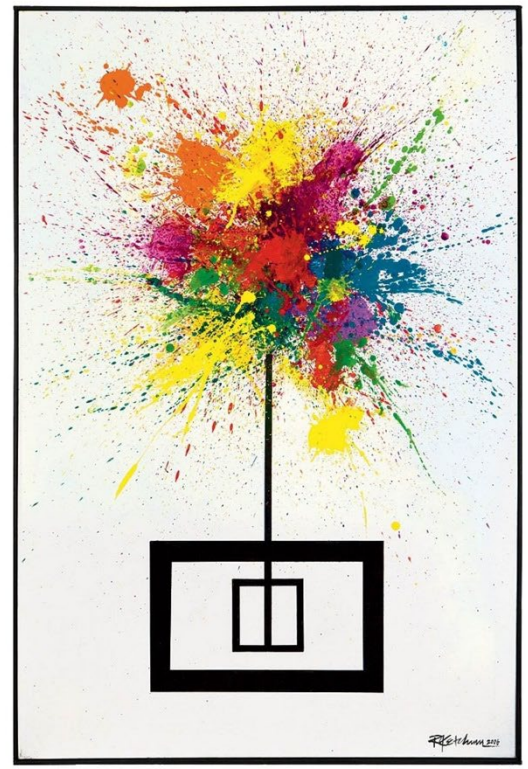
This webinar is being recorded.

Q&A Webinar

June 23, 2022 @ 1:00 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 Transformative_Awards@mail.nih.gov
- Webinar recording & slides will be posted on website at commonfund.nih.gov/tra
- For more application guidance, see our Application & Award Guide on website (includes example applications)

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

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

Panelists

Ravi Basavappa, Ph.D.

Program Leader
Office of the Director

Becky Miller, Ph.D.

Program Officer
Office of the Director

Trish Labosky, Ph.D.

Program Leader
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

Mei-Ching Chen, Ph.D.

Informatics Team Lead
Center for Scientific Review

Tony Kirilusha, Ph.D.

Program Director
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Common Fund Programs

- 4D Nucleome (4DN)
- Acute to Chronic Pain Signatures (A2CPS)
- Bridge to Artificial Intelligence (Bridge2AI)
- Cellular Senescence Network (SenNet)
- 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
- Glycoscience
- 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)
- Illuminating the Druggable Genome (IDG)
- Knockout Mouse Phenotyping (KOMP)
- Library of Integrated Network-Based Cellular Signatures (LINCS)
- 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: FOAs, access to high-end instruments, databases, reagents, protocols, ...

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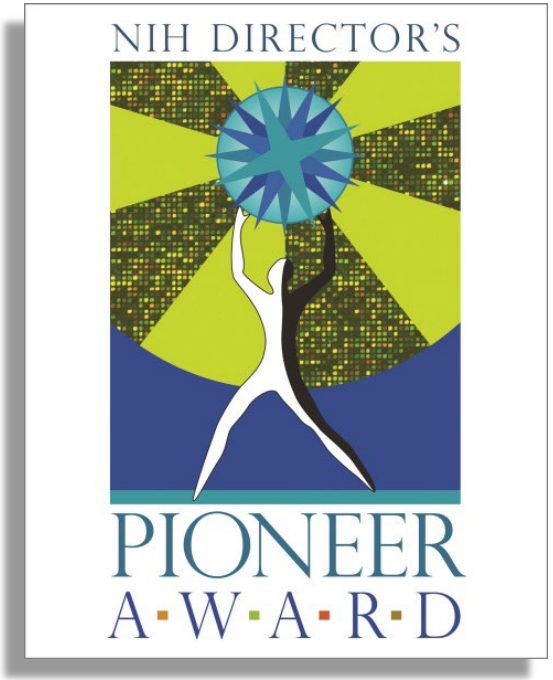
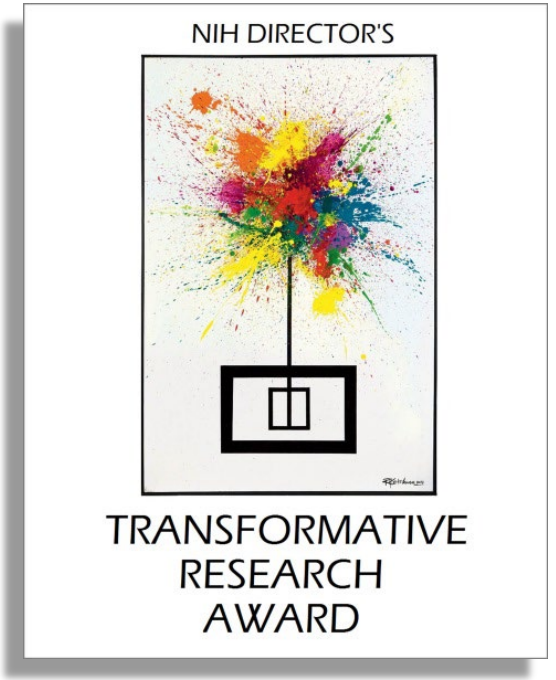
High-Risk, High-Reward Research Program





Supporting outstanding scientists at all career stages proposing 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

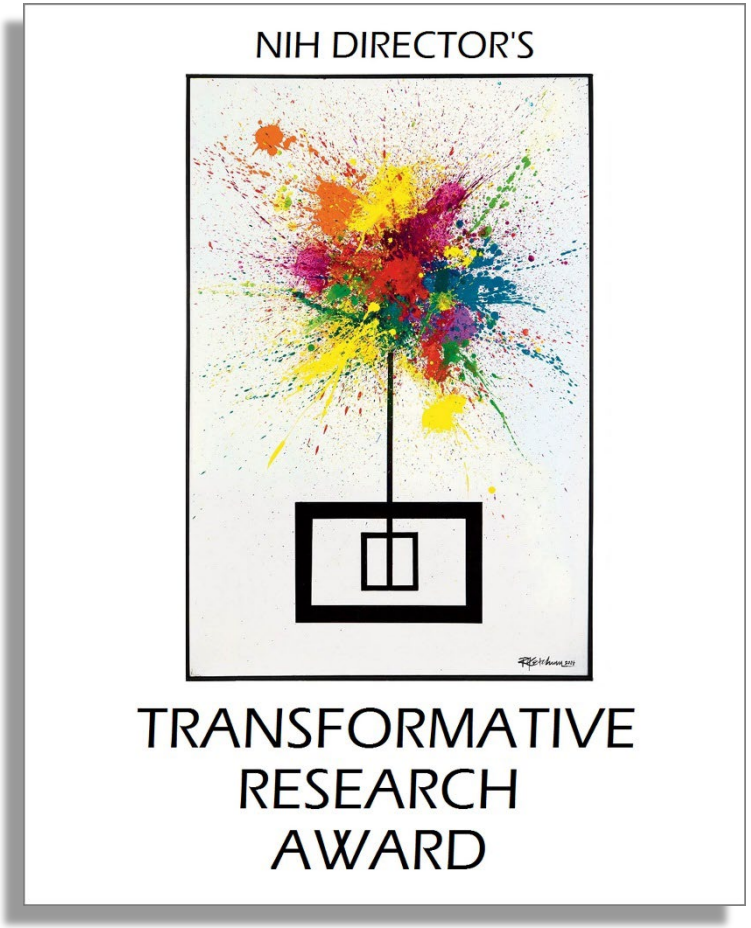
HRHR Working Group

Chair
James Anderson (OD)

Program Leader
Ravi Basavappa (OD)

Members
Kristin Abraham (NIDDK)
Hugh Auchincloss (NIAID)
Abraham Bautista (NIAAA)
Sangeeta Bhargava (NEI)
Gene Carstea (CSR)
Robert Carter (NIAMS)
Jennifer Collins (NIEHS)
Christine Colvis (NCATS)
Emmeline Edwards (NCCIH)
Zeynep Erim (NIBIB)
Rene Etcheberrigaray (NIA)
Nancy Freeman (NIDCD)
Dana Greene-Schloesser (OD)
Jane Hettinger (NINDS)
Gabriel Hidalgo (NIDCR)
Ray Jacobson (CSR)
Flora Katz (FIC)
Anthony Kirilusha (NIAMS)
Susan Koester (NIMH)
Trish Labosky (OD)
James Li (CSR)
Roger Little (NIDA)
James Mack (CSR)
Becky Miller (OD)
Brett Miller (NICHD)
Daniel Miller (NINDS)
David Miller (NCI)
Michael Morse (OD)
Ellie Murcia (OD)
Imoh Okon (CSR)
Richard Palmer (NLM)
Steven Pittenger (NCATS)
Srikanth Ranganathan (CSR)
Diana Rutberg (NIDCR)
Suzanne Ryan (CSR)
John Satterlee (NIDA)
Carol Shreffler (NIEHS)
Lillian Shum (NIDCR)
Darren Sledjeski (NIGMS)
Heidi Sofia (NHGRI)
Barbara Sorkin (OD)
Nathaniel Stinson (NIMHD)
Stephanie Webb (NHLBI)
Elizabeth Wilder (OD)

High-Risk, High-Reward Research Program



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

R01 Application (but used in 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)

Research Strategy Considerations

- 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 (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

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.

- Results are encouraging:
  - substantial fraction of applicants incentivized to apply because of anonymization
  - overall, applicants were still able to prepare applications that conveyed innovation and impact
  - reviewers were still able to evaluate innovation and impact with information at hand

- Pilot is continuing for third year (last year)

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.

TRA Anonymization of Application

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.**

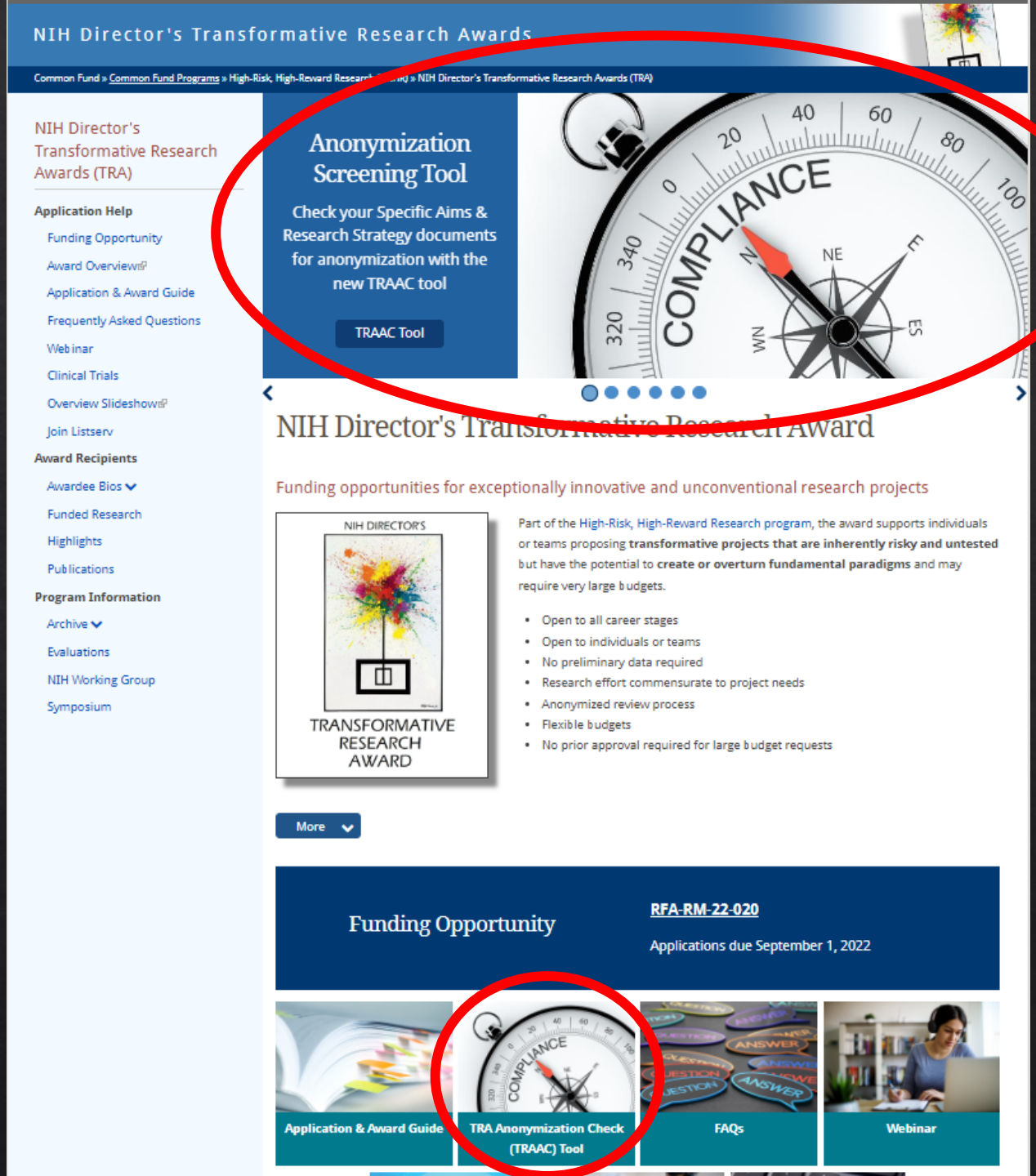
Describe investigator suitability for the proposed research in the biosketch.

TRA Anonymization Check (TRAAC) Tool

New automated tool to help screen Specific Aims page and Research Strategy section for anonymization

Scans documents for items that could violate anonymization requirements (e.g., names of individuals or institutions, honors and awards, hyperlinks, references, and other identifiable text)

- Potential violations are highlighted in the document and returned for reference
- Meant for general guidance only
- Cannot infer meaning or comprehend complex references
- Does not provide ultimate, definitive judgement on anonymization
- Designed to err on the side of false positives
- PI(s) responsible for deciding on text to include
- All submitted applications still be screened by NIH staff and are subject to withdrawal if not responsive



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U.S. Department of Health & Human Services

NIH A Collaboration Between the Center for Scientific Review and the Office of Strategic Coordination - The Common Fund

Sign In RAAC Support

Login.gov

TRA Anonymization Check (TRAAC)

Transformative Research Award Anonymization Check (TRAAC) is an automated tool to help screen the Specific Aims page and Research Strategy section for anonymization in response to the NIH Director's Transformative Research Award funding opportunity announcement. TRAAC scans documents for items that could violate anonymization requirements, such as names of individuals or institutions, honors and awards, hyperlinks, references, and other identifiable text. Potential violations are highlighted in the document and returned to the user for their reference.

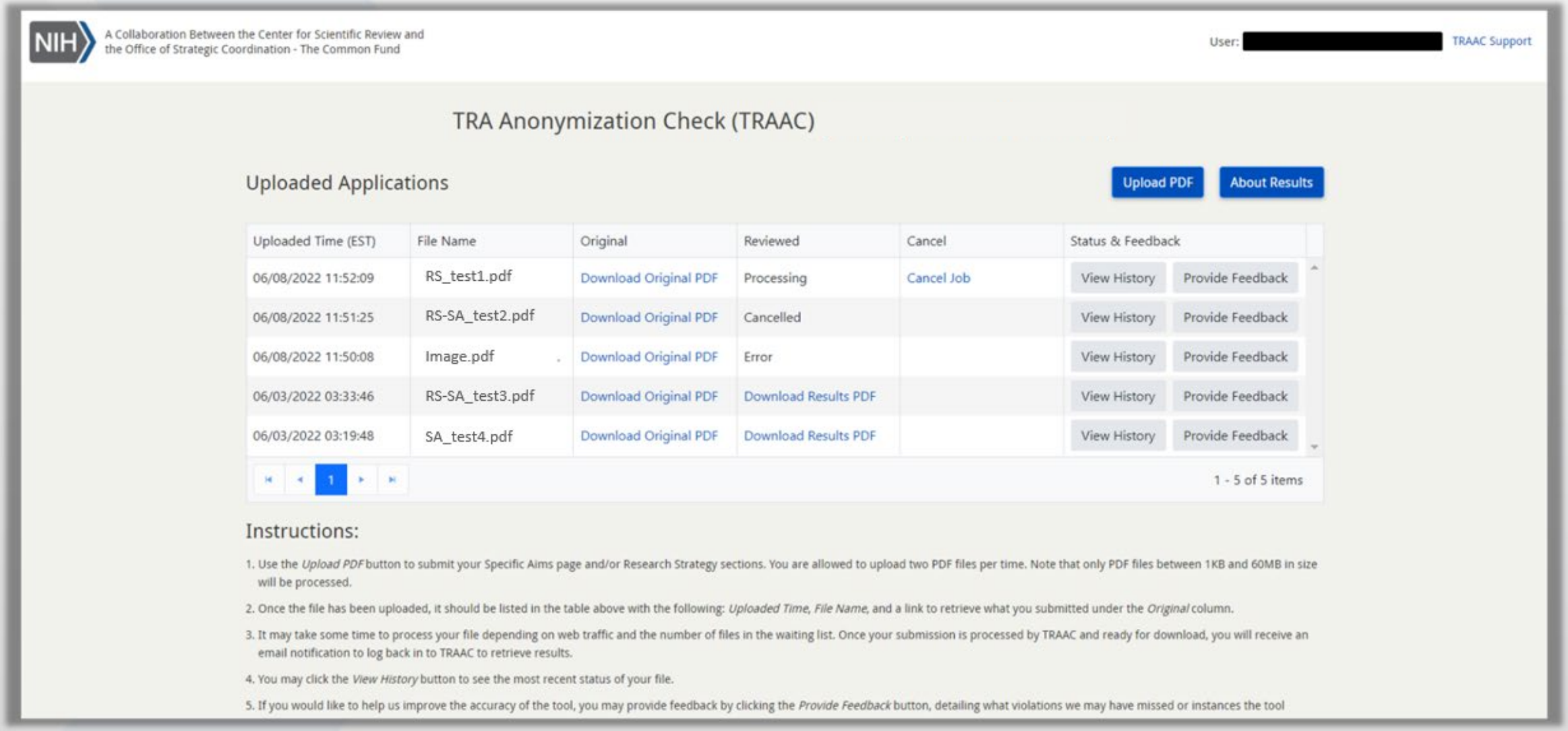
1. Sign In with your Login.gov account or create one.
2. Upload a PDF of your Specific Aims page and/or Research Strategy sections and hit the Submit button. Files must be machine readable PDF files (max size 60MB).
3. Please note that this is not a real-time response system. An email will notify you when your submission is processed and ready for download.

The TRAAC website relies on a machine process to extract the text within submitted PDFs. This may lead to some PDF formats being processed in unexpected ways. If you created your document using Microsoft Word, we would suggest that you save your files directly as a PDF using the "Save As" function, and not the "Print to PDF" function or other equivalents, in order for your submission to be processed successfully.

Disclaimer: TRAAC is a screening tool meant to provide general guidance only. It cannot infer meaning or comprehend complex references. Anonymization instructions in the Funding Opportunity Announcement (FOA) take precedence over any information provided by TRAAC and should be referred to for complete and comprehensive directions. TRAAC does not provide an ultimate, definitive judgement on anonymization. It is designed to err on the side of false positives and so may flag terms (such as Watson-Crick or CDC) that do not breach anonymity and can be retained in the text. The responsibility for the text to include is borne by the PI(s). All submitted applications will still be screened by NIH staff and are subject to withdrawal if not responsive to the FOA instructions.

drm.csr.nih.gov/traac/home

TRAAC System – Dashboard



A Collaboration Between the Center for Scientific Review and the Office of Strategic Coordination - The Common Fund

User: [redacted] TRAAC Support

TRA Anonymization Check (TRAAC)

Uploaded Applications

Upload PDF | About Results

Uploaded Time (EST)	File Name	Original	Reviewed	Cancel	Status & Feedback
06/08/2022 11:52:09	RS_test1.pdf	Download Original PDF	Processing	Cancel Job	View History / Provide Feedback
06/08/2022 11:51:25	RS-SA_test2.pdf	Download Original PDF	Cancelled		View History / Provide Feedback
06/08/2022 11:50:08	Image.pdf	Download Original PDF	Error		View History / Provide Feedback
06/03/2022 03:33:46	RS-SA_test3.pdf	Download Original PDF	Download Results PDF		View History / Provide Feedback
06/03/2022 03:19:48	SA_test4.pdf	Download Original PDF	Download Results PDF		View History / Provide Feedback

1 - 5 of 5 items

Instructions:

1. Use the *Upload PDF* button to submit your Specific Aims page and/or Research Strategy sections. You are allowed to upload two PDF files per time. Note that only PDF files between 1KB and 60MB in size will be processed.
2. Once the file has been uploaded, it should be listed in the table above with the following: *Uploaded Time*, *File Name*, and a link to retrieve what you submitted under the *Original* column.
3. It may take some time to process your file depending on web traffic and the number of files in the waiting list. Once your submission is processed by TRAAC and ready for download, you will receive an email notification to log back in to TRAAC to retrieve results.
4. You may click the *View History* button to see the most recent status of your file.
5. If you would like to help us improve the accuracy of the tool, you may provide feedback by clicking the *Provide Feedback* button, detailing what violations we may have missed or instances the tool

- Output:
  Highlighted text of possible anonymization violations

- Designed to err on the side of false positives:
  Will, for example, flag “Watson-Crick,” “ELISA,” and “Agilent Technologies”

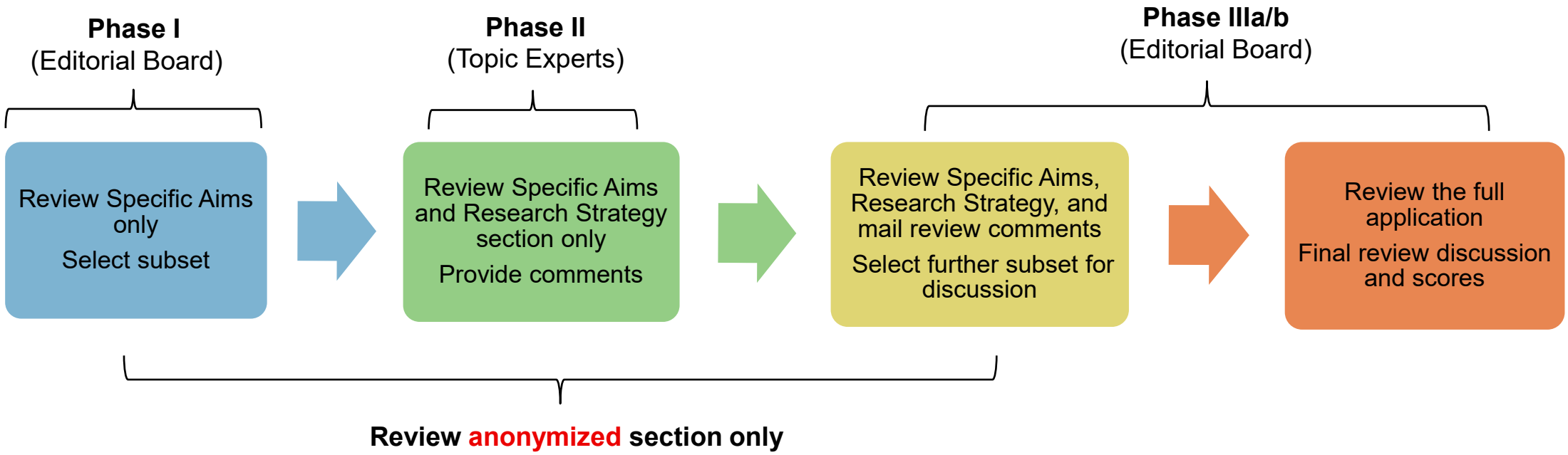
- Provides general guidance only:
  Applicant is responsible for deciding what text to include in application

- Voluntary to use:
  But, could be useful in catching breaching text that slips through

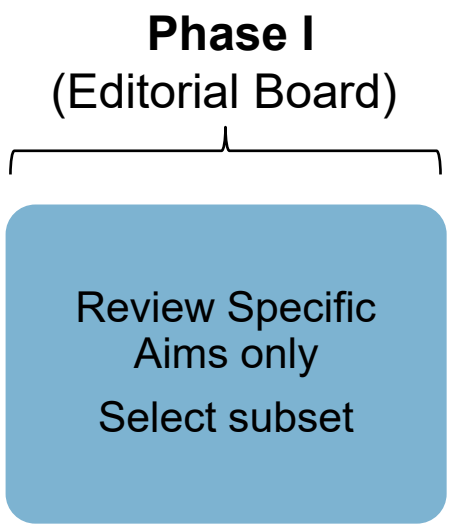
Review Process for the NIH Director's Transformative Research Awards (RFA-RM-22-020)

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

Overview of Multi-stage Editorial Board Review Process



Phase I: Initial Editorial Review of Applications

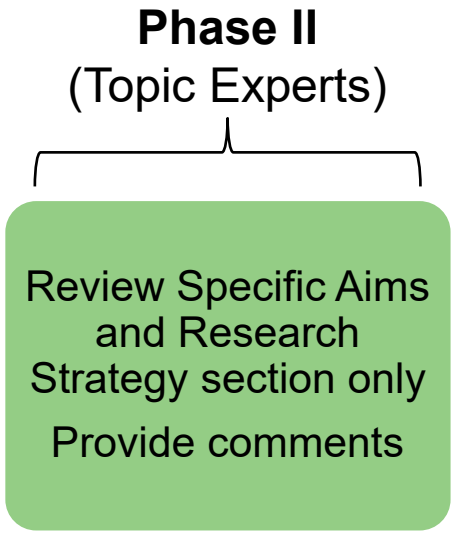


Timeline:

- **NIH Admin Review (anonymization): early - mid September**
- **Phase I Review: late September to mid November, 2022**

- 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



- 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.

Timeline:

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

Phase IIIa: Editorial Review and Preliminary Score

Phase IIIa
(Editorial Board)

Review Specific Aims, Research Strategy, and mail review comments

Select further subset for discussion

Timeline:

- **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 review comments 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

Phase IIIb: Review Discussion and Final Score

Phase IIIb
(Editorial Board)

Review the full application

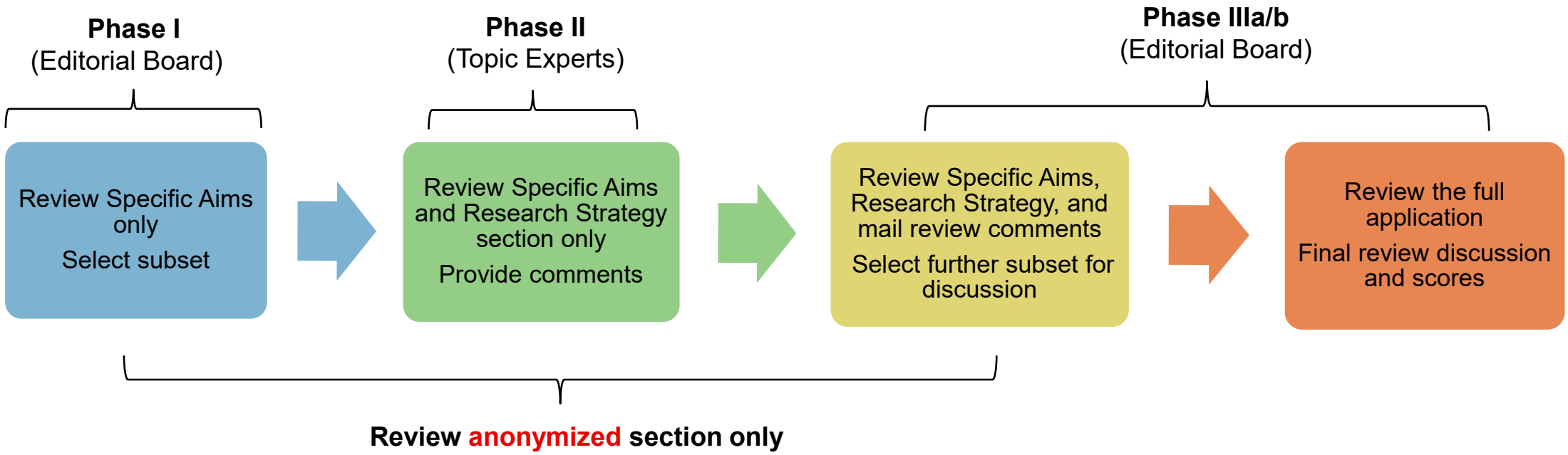
Final review discussion and scores

Timeline:

- **Phase IIIb: late March 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 entire application, and input from panel discussion and the mail review.

Overview of Multi-stage Editorial Board Review Process



- No interim review results will be released
- Contact PI won't see the application status during anonymized review phase(s) on eRA Commons Account

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Eligibility

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Application & Submission

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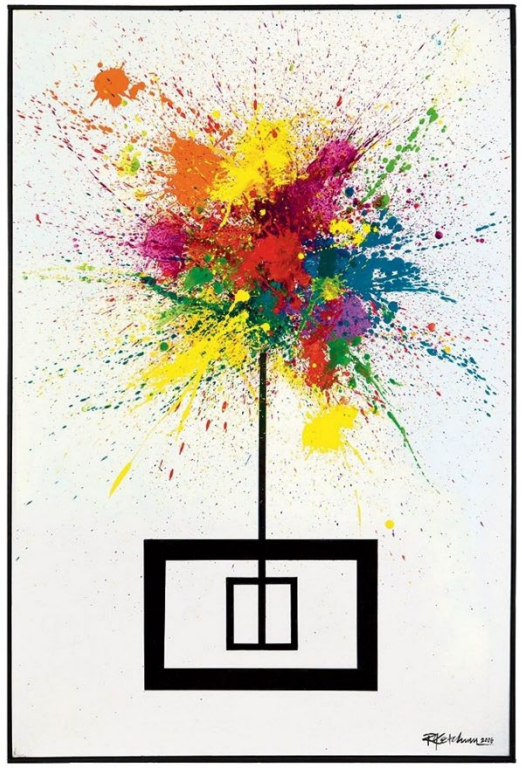
Budget



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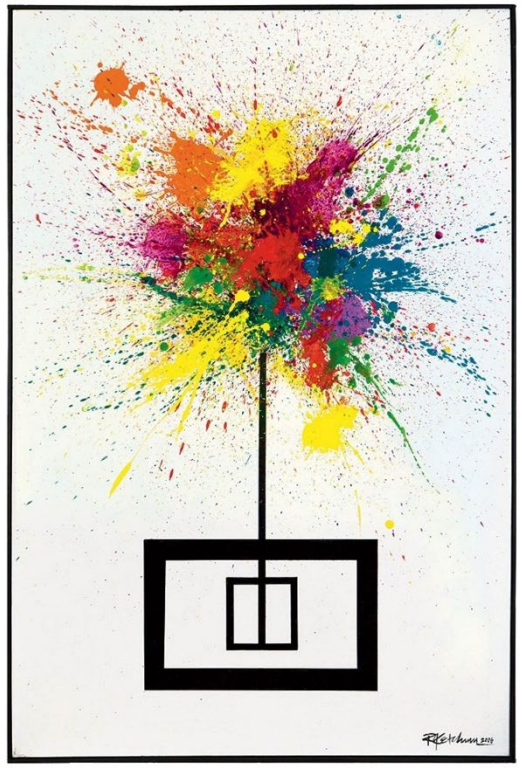

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