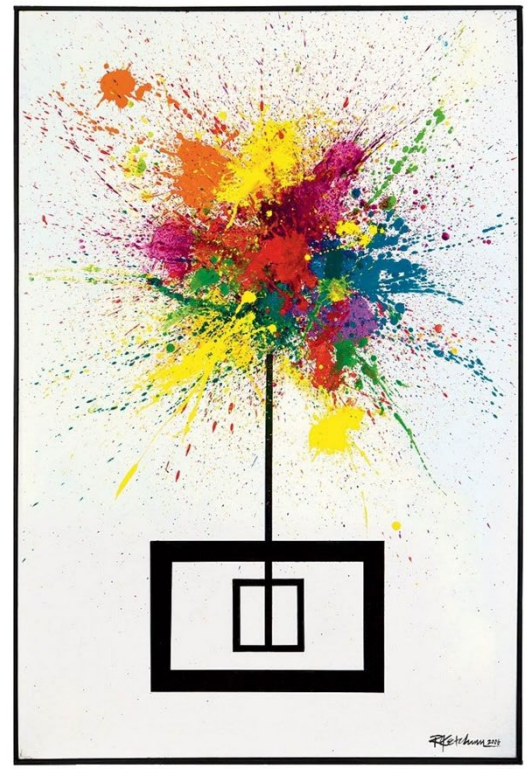
This webinar is being recorded.

Q&A Webinar

June 26, 2024 @ 3:30 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

commonfund.nih.gov/tra

Transformative_Awards@mail.nih.gov

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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

Trish Labosky, Ph.D.

Program Leader
Office of the Director

Elena Smirnova, 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

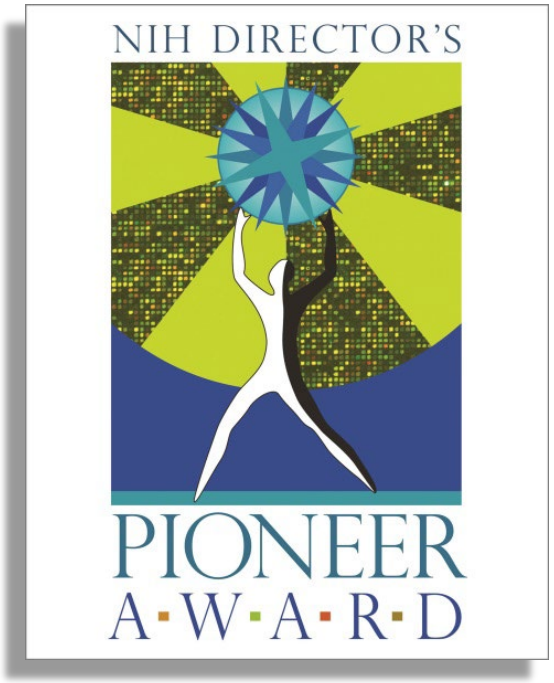
High-Risk, High-Reward Research Program

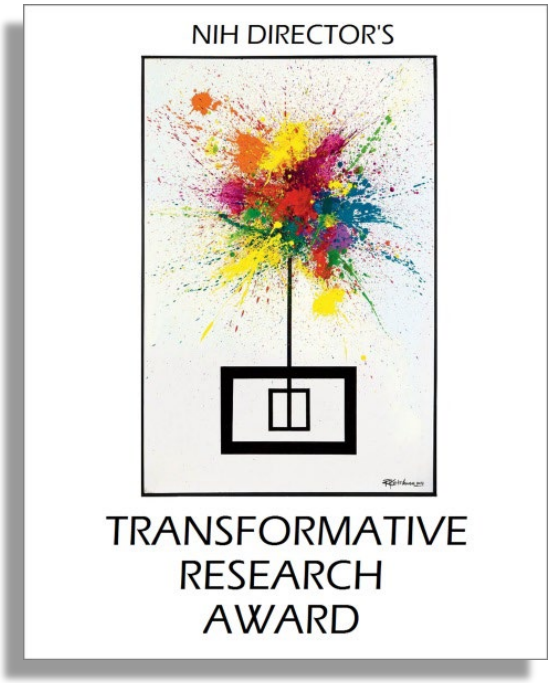
Annual funding opportunities

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

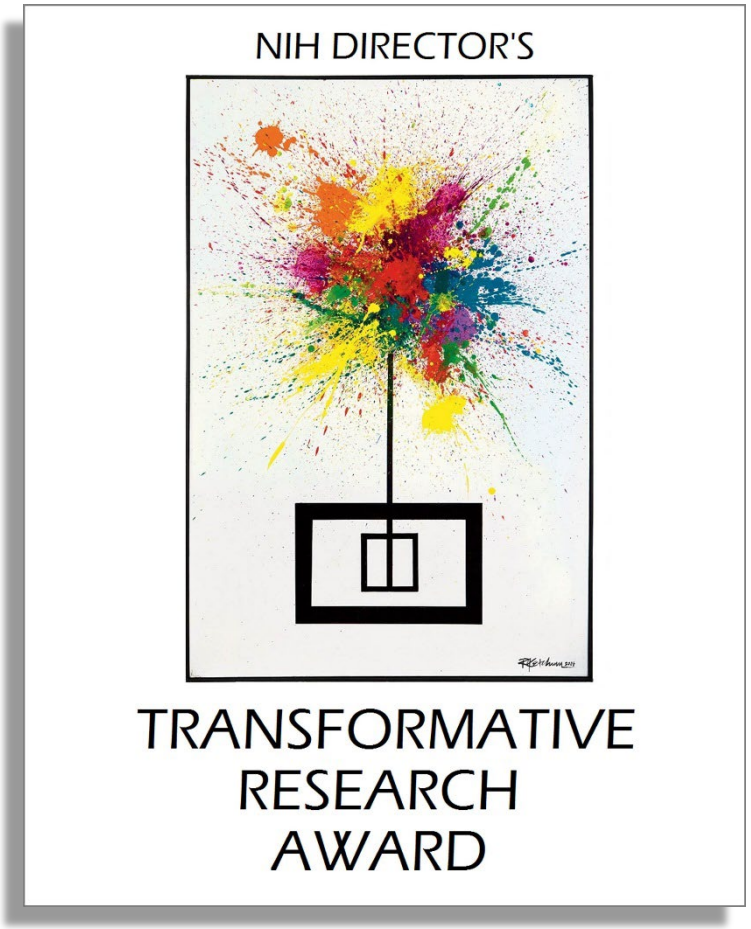
HRHR Working Group

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 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
- Anonymized review process

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:
	  o Significance, Innovation, Impact
	  o 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:
	  o Overview of research project (set context for project)
	  o Approach (describe underlying logic and will ensure robustness and rigor)
	  o Innovation (explain why exceptionally innovative)
	  o Appropriateness for TRA (explain why HRHR and not traditional R01)
	  o 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 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 fifth 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

NIH Director's Transformative Research Award

WATCH THE VIDEO

Home » High-Risk, High-Reward Research (HRHR) » NIH Director's Transformative Research Award

NIH Director's Transformative Research Award

Application Help
- Funding Opportunity
- Award Overview
- Application & Award Guide
  - Eligibility
  - Application Process
  - Sample Applications
  - After Submission
  - Award Management
- Frequently Asked Questions
- Webinar
- Clinical Trials
- Join Listserv

Award Recipients
- Awardee Bios

Program Information
- Science Highlights
- Program Publications
- Funded Research
- Archive
- Evaluations
- NIH Working Group
- Symposium

Program Snapshot

Part of the High-Risk, High-Reward Research program, the award supports individuals or teams proposing **transformative projects that are inherently risky and untested** but have the potential to **create or overturn fundamental paradigms** and may require very large budgets.

- Open to all career stages
- Open to individuals or teams
- No preliminary data required
- Research effort commensurate to project needs
- Anonymized review process
- Flexible budgets
- No prior approval required for large budget requests

See the Award Overview for more information.

RFA-RM-24-004

Applications due September 3, 2024

Funding Opportunity

Information & Help

TRA ANONYMIZATION CHECK (TRAAC) TOOL

APPLICATION & AWARD GUIDE

FAQS

WEBINAR

OVERVIEW SLIDESHOW

CLINICAL TRIALS

HRHR LISTSERV & EMAILS

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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)

NIH DIRECTOR'S

TRANSFORMATIVE RESEARCH AWARD

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 (FOA) . 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 as defined in the FOA . Potential violations are highlighted in the document and returned to the user for their reference. **This tool is intended only for general guidance, the PI must make final decisions concerning text to include.**

1. Sign In with your Login.gov account or create an account.
2. Upload a PDF of your Specific Aims page and/or Research Strategy sections **without bibliography** and hit the Submit button. Files must be machine readable PDF files (max size 60MB).
3. Please note, this is not a real-time response system. An email will notify you when your submission is processed and ready for download. Please do not wait to use this tool until the application due date. The process takes 45 minutes on average to complete. Depending on number of concurrent submissions to the tool, it may take longer than expected. If your file was in process for over 24 hours, please contact NIH TRAAC Support Team.
4. Please note, TRAAC does not store your submitted documents long term. If you submitted documents last year, they have been removed from the system and will no longer show in your account.

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 suggest 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 is borne by the PI(s). All submitted applications will be independently screened by NIH staff and are subject to withdrawal if not responsive to the FOA instructions.

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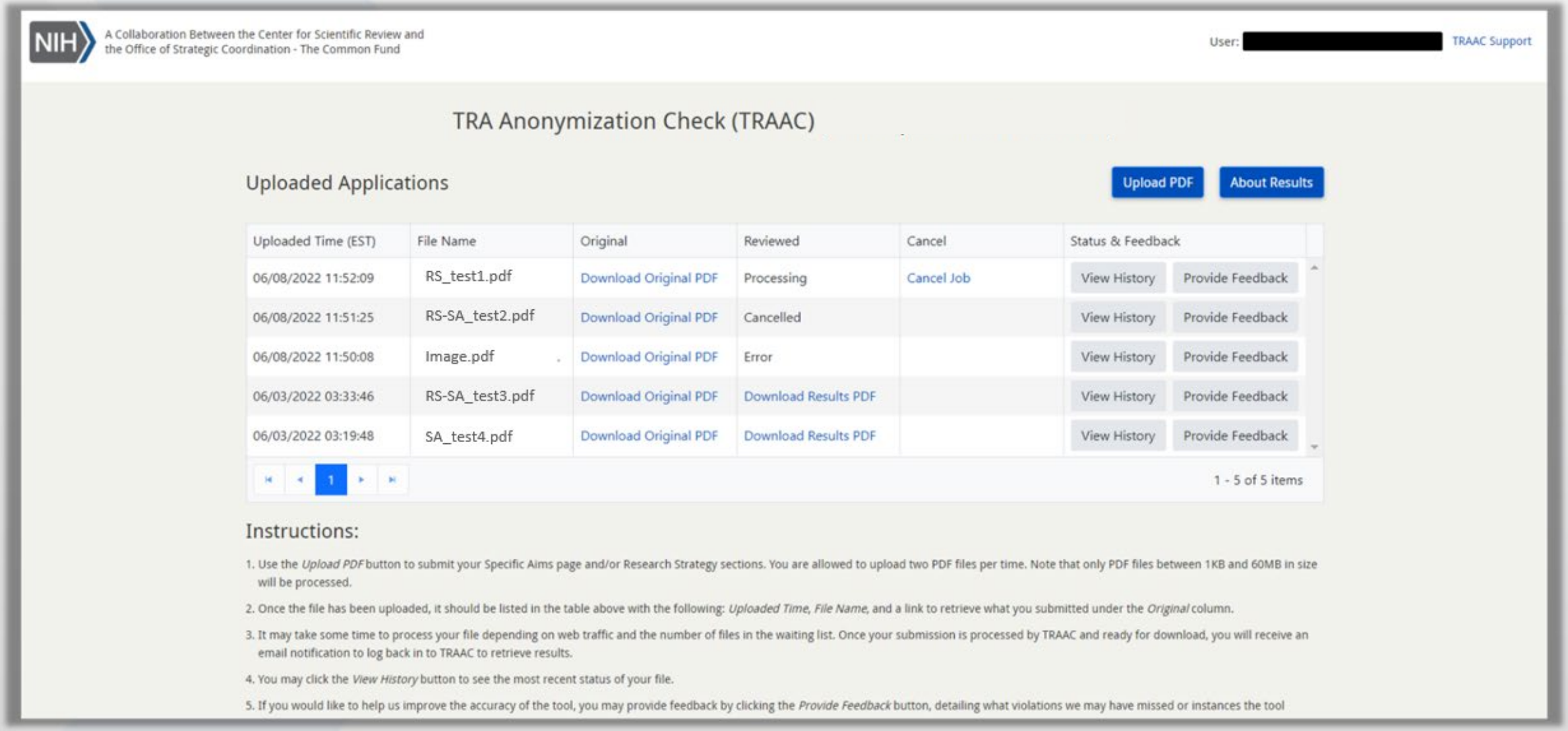
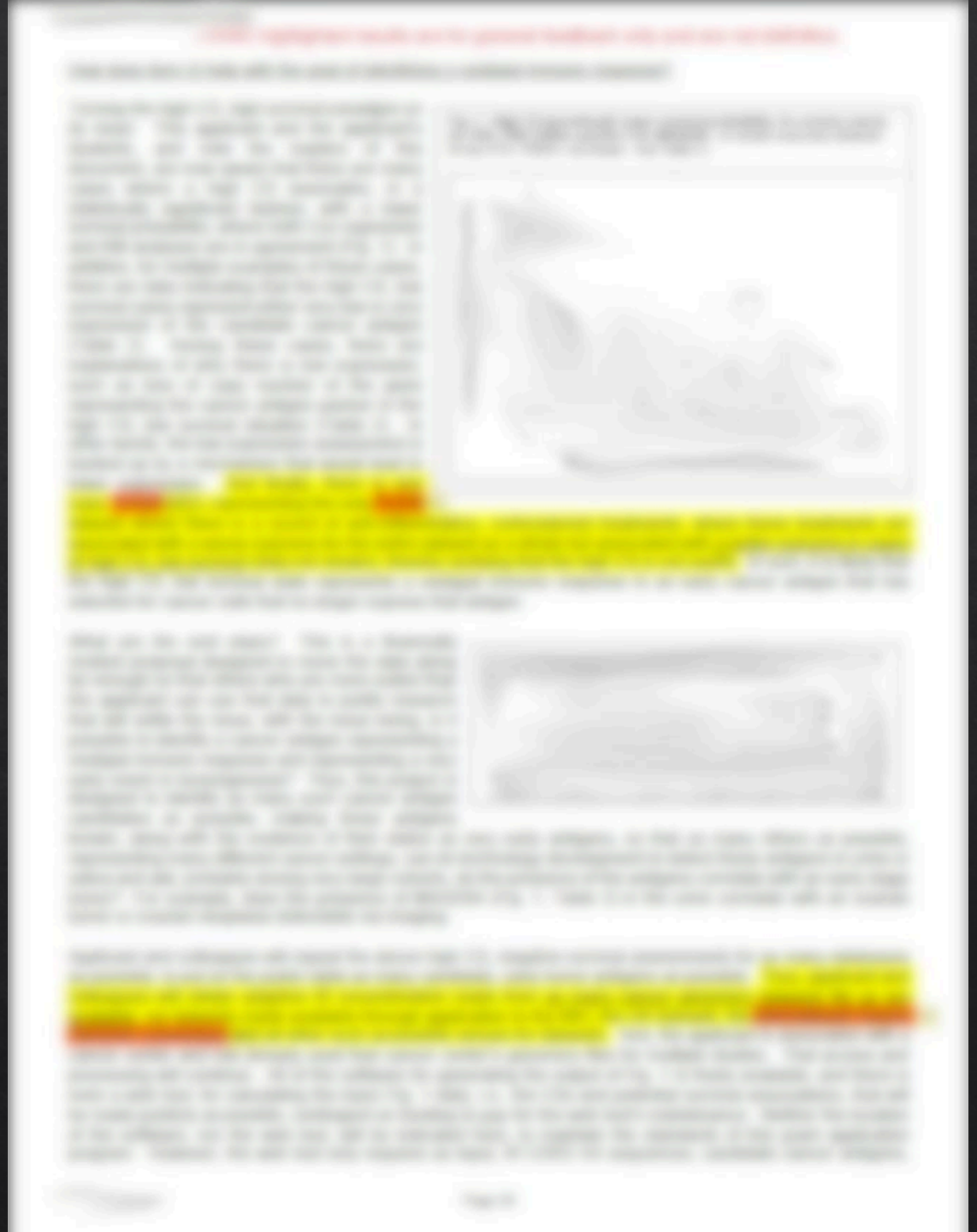
drm.csr.nih.gov/traac/home

TRAAC System – Dashboard





- **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

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

Sign In | TRAAC Support

TRA Anonymization Check (TRAAC)

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1. Sign In with your Login.gov account or create an account.
2. Upload a PDF of your Specific Aims page and/or Research Strategy sections **without bibliography** and hit the Submit button. Files must be machine readable PDF files (max size 60MB).
3. Please note, this is not a real-time response system. An email will notify you when your submission is processed and ready for download. Please do not wait to use this tool until the application due date. The process takes 45 minutes on average to complete. Depending on number of concurrent submissions to the tool, it may take longer than expected. If your file was in process for over 24 hours, please contact NIH TRAAC Support Team.
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Click here for help with TRAAC tool

drm.csr.nih.gov/traac/home

Data Management & Sharing Plans

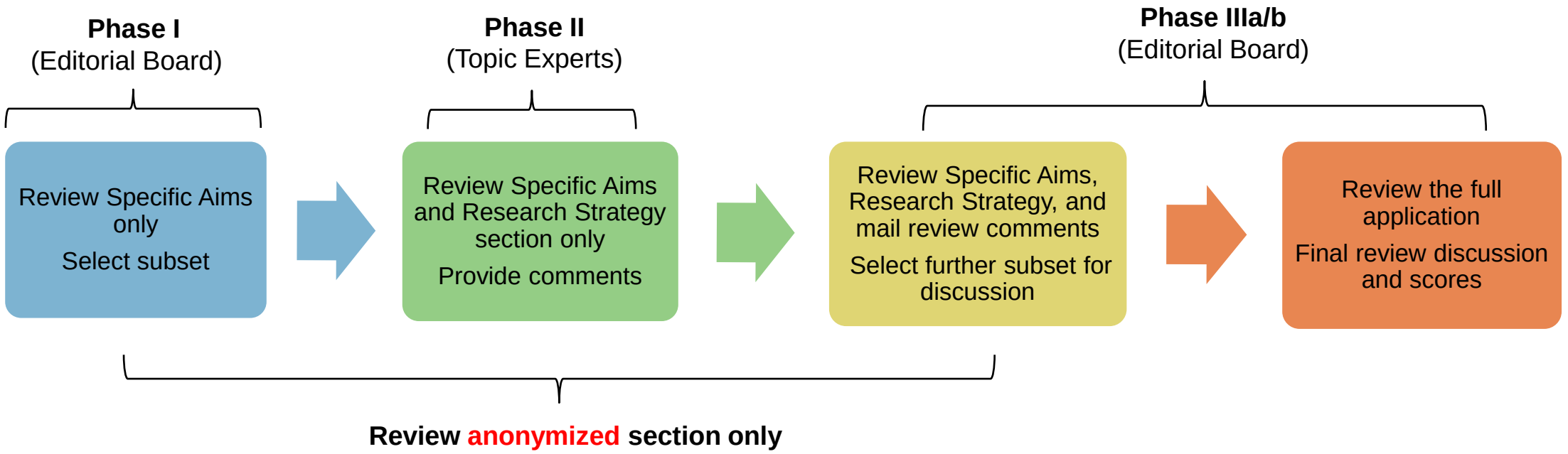
Plans should explain how scientific data generated by the research project will be managed and which scientific data and metadata will be shared

- 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** for more information & examples

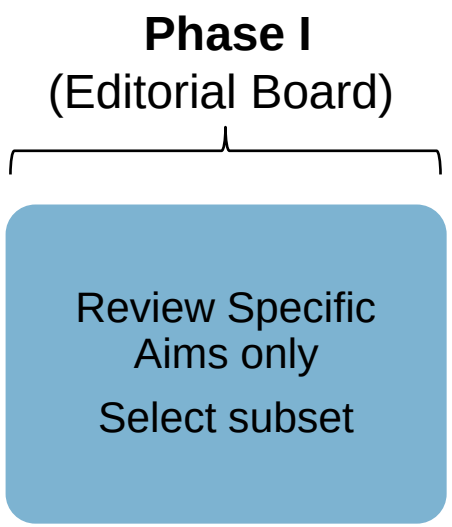
Review Process for the NIH Director's Transformative Research Awards (RFA-RM-24-004)

Elena Smirnova, Ph.D.
Chief, Molecular Genetics and
Genomics Review Branch
NIH Center for Scientific Review
smirnove@csr.nih.gov

Overview of Multi-stage Editorial Board Review Process



Phase I: Initial Editorial Review of Applications



Timeline:

- **Applications due September 3, 2024**
- **NIH Admin Review (anonymization): early - mid September**
- **Phase I Review: late September to mid-November 2024**

- 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 application is reviewed by 4 editors
- 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
- Top scoring subset of applications plus any rescues are advanced to Phase II

Phase II: Technical Review of Applications

Phase II
(Topic Experts)

Review Specific Aims and Research Strategy section only

Provide comments

- 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 Aims 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 2024 to mid-February 2025**
- **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 2025**
- **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

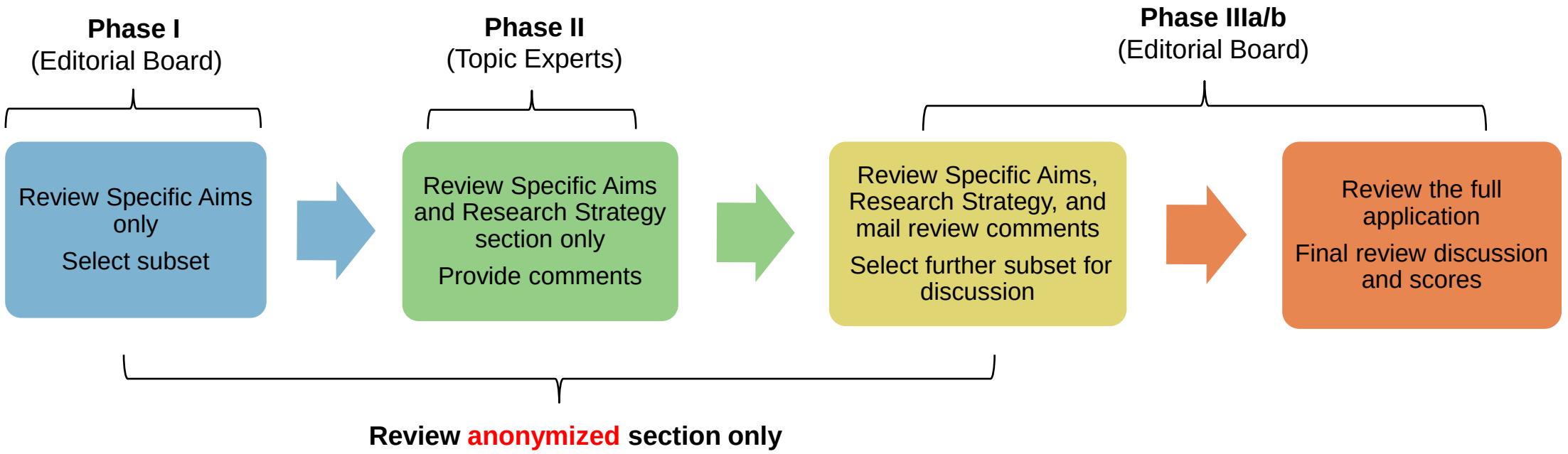
Final review discussion and scores

Timeline:

- **Phase IIIb: late March 2025**
- **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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Q&A Webinar

June 26, 2024 @ 3:30 PM EDT

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

Eligibility

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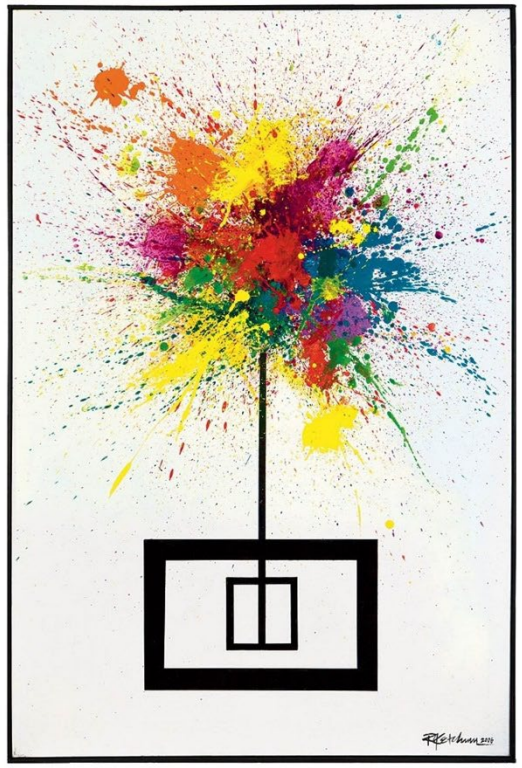
Application & Submission



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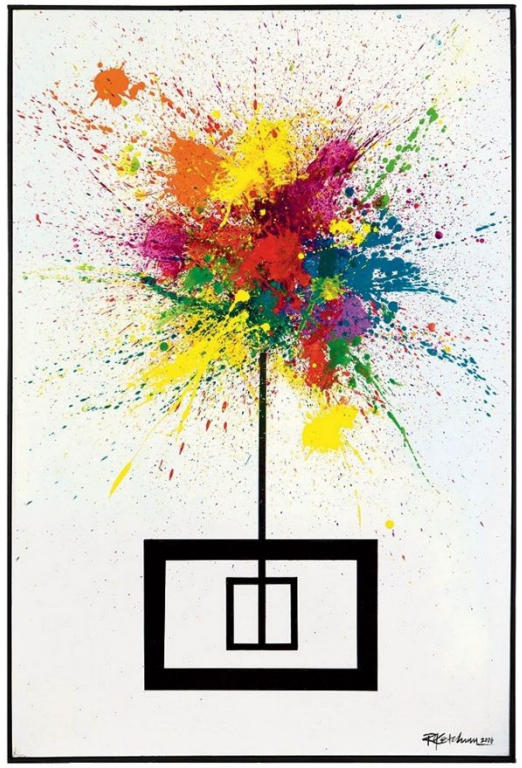
Budget



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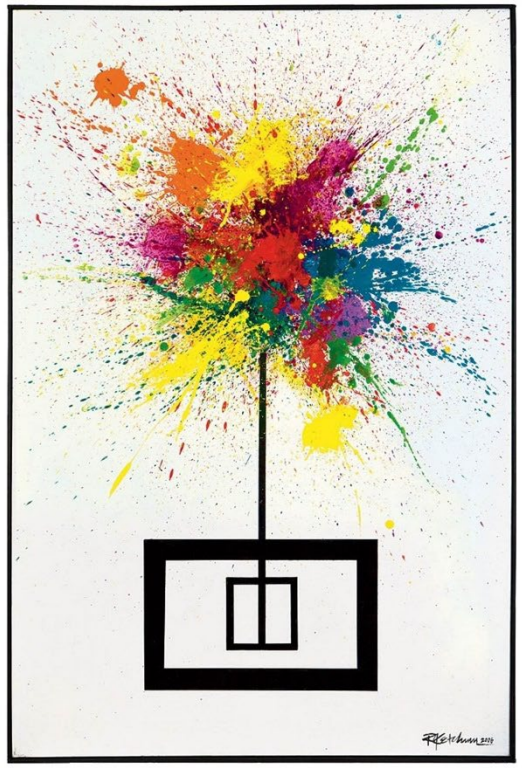
Review



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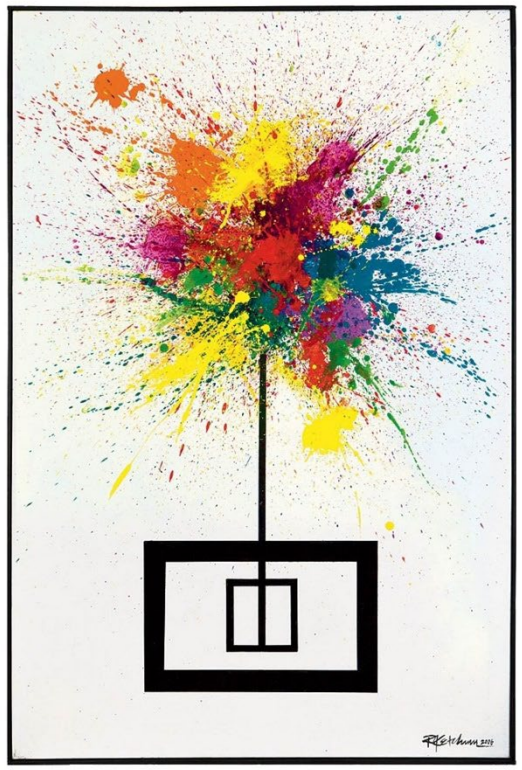

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