

OSC (Common Fund)



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Concept Clearance: Continuation of the High Risk/High Reward Program

NIH Director's Pioneer Award Program (DP1 Clinical Trial Optional)

NIH Director's New Innovator Award Program (DP2 Clinical Trial Optional)

NIH Director's Transformative Research Award Program (R01 Clinical Trial Optional)

NIH Director's Early Independence Award Program (DP5 Clinical Trial Optional)

Objective: to foster scientific leaps by supporting individuals of exceptional creativity who propose unusually innovative research with the potential for broad impact, emphasizing the development of the next generation of scientists

Funds Available and Anticipated Number of Awards: \$97.4M in FY2020; 57 awards

(7 Pioneer Awards, 33 New Innovator Awards, 7 Transformative Research Awards, 10 Early Independence Awards)

Award Project Period: 5 years

Council Action: Vote on continued support of High-Risk, High-Reward Research Program and its four initiatives

Presentation overview



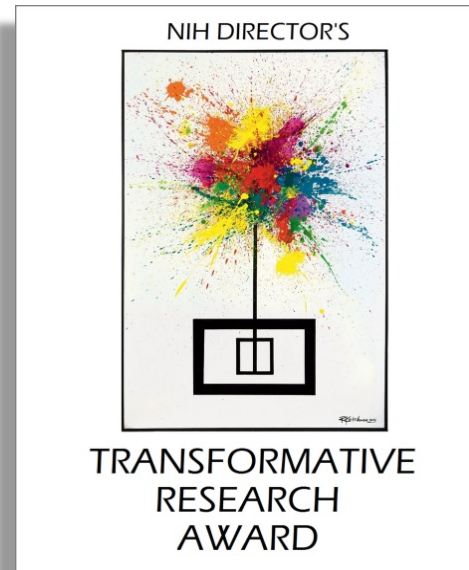
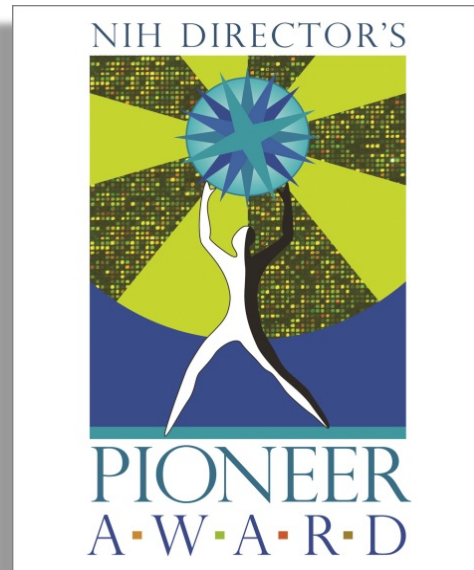
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- The High-Risk, High-Reward Research (HRHR) Program and its constituent initiatives
- Findings and recommendations of the ACD Working Group on HRHR Program
- NIH response and implementation plan, noting how it affects the HRHR FOAs
- Proposed anonymized review process for the Transformative Research Award initiative
- Discussion
- Vote to renew the HRHR program through reissue of the HRHR FOAs

High-Risk, High-Reward Research Program



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- Foster scientific leaps
- No preliminary data or detailed experimental plan required
- Uses non-standard application formats and review processes
- Any topic within the broad mission of NIH is welcome (“investigator-initiated”)
- Program not subject to 10-year time limit, individual awards limited 5 years
- Common Fund budget for competing awards in 2020: \$97.4M

High-Risk, High-Reward Working Group



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Chair

James M. Anderson, MD, PhD
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OD, NIH

Program Leader

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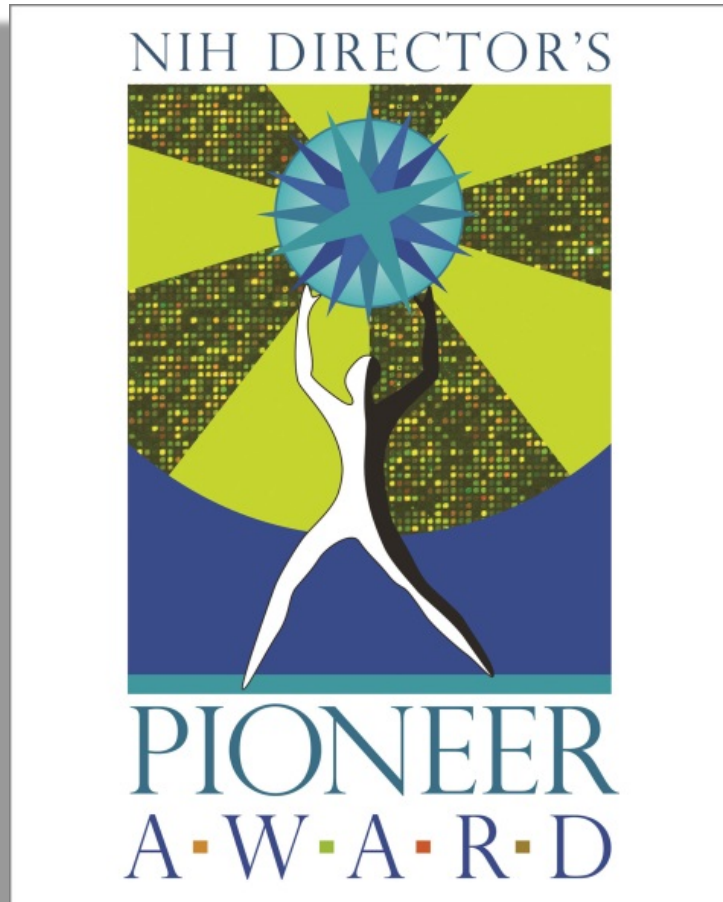
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High-Risk, High-Reward Research Program



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Supports individual scientists with outstanding records of creativity proposing new perspectives on major biomedical or behavioral challenges

- Open to all career stages
- Must be new research direction
- \$700,000 in direct cost per year, allows ambitious ideas
- Major portion of research effort (at least 51%)
- Five-page essay focuses on overall idea, its innovation, its potential impact, suitability for Pioneer Award initiative
- Two-phase review process – mail review of all applications followed by in-person interviews of most meritorious ~25 applicants by a panel of generalists
- Flexibility to change research direction

High-Risk, High-Reward Research Program



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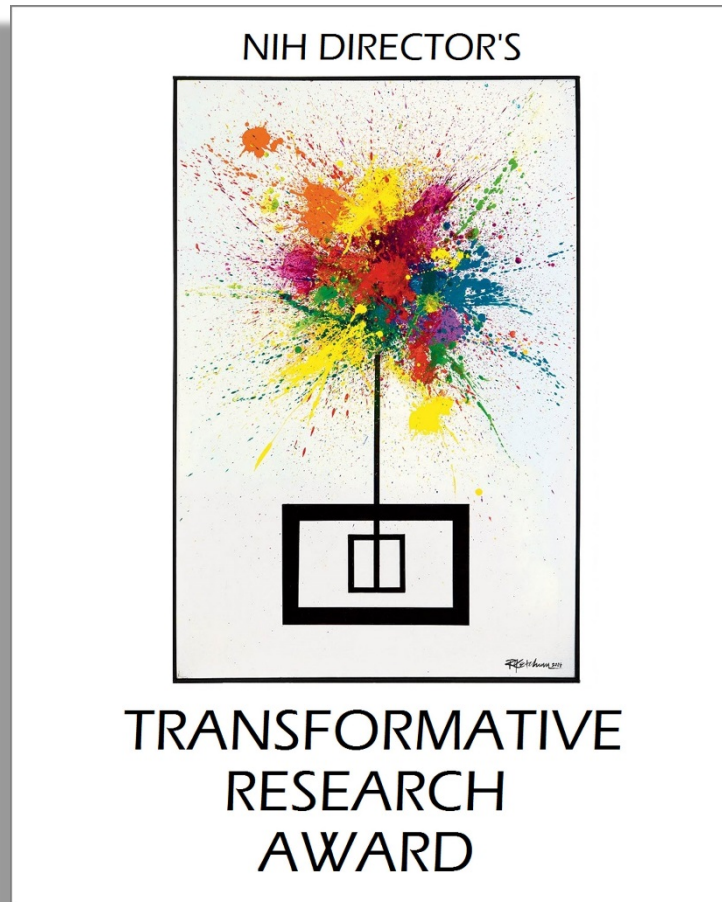
Supports unusually creative ***early stage investigators*** proposing innovative, high-impact research

- In spirit, similar to Pioneer Award, but restricted to Early Stage Investigators
- Commit 25% research effort
- Awards of \$1.5 million in direct costs disbursed in first year of ~5 year project period
- Ten-page essay emphasizes focuses on overall idea, innovation, potential impact, innovation history of PI, and suitability of project for New Innovator Award
- Two-phase review process – mail review of all applications followed by a discussion of ~18-20% by a panel of generalists

High-Risk, High-Reward Research Program



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Supports unusually innovative and impactful research projects led by ***individuals or teams*** and allows ***flexible budgets***

- Open to single-PI or multi-PI applications
- No fixed budget
- Three-phase review process
- Compared to Pioneer and New Innovator reviews, more emphasis on project and less on person
- Though more project focused, no preliminary data or conventional R01-level of experimental detail expected

High-Risk, High-Reward Research Program



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Enables outstanding early career scientists to move rapidly into independent research positions by ***skipping the traditional postdoc***

- Tight eligibility window: finish research degree or clinical training within +/- 1 yr. application
- Requires substantial support and commitment of host institution; so, up to two applications per institution
- Commit 80% effort to independent research
- Provides R01-level support (\$250,000 direct costs/year)
- Two-phase review process – mail review of all applications in first phase followed by discussion of ~30 applications by a panel of generalists (testing discussion vs. interviews)

Independent evaluations of HRHR initiatives



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- Pioneer Award outcomes evaluation conducted by the Science and Technology Policy Institute (STPI) in 2012
 - Found that research by Pioneer Awardees tends to be more innovative and impactful than matched, similarly qualified R01 investigators and about the same as HHMI investigators
- New Innovator Award outcomes evaluation conducted by STPI in 2016
 - Found that research by New Innovator Awardees tends to be more innovative and impactful than matched ESI R01 investigators
 - Impact of New Innovator Award on the careers of its recipients about the same as impact of R01 on its recipients
- Transformative Research Award and Early Independence Award evaluations currently underway

ACD High-Risk, High-Reward Working Group



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Nicole Perry
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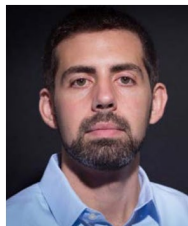
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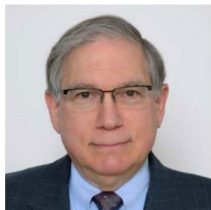
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Jason Sheltzer, Ph.D.
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Lawrence Tabak,
D.D.S., Ph.D. (Co-Chair)
Office of the Director, NIH



Hannah Valentine, M.D.
OD Scientific Workforce
Diversity, NIH

- The NIH Director convened a High-Risk High-Reward Research Working Group of his Advisory Committee to Director (ACD) in 2018
- The Working Group (WG) was tasked with:
1) evaluating the effectiveness of the HRHR program and 2) assessing matters of diversity and potential bias (for gender, underrepresented groups, institutions, and topics)



WG findings (presented to ACD in June 2019):

- Overall successful program
- In general, female and URG investigators are not being adversely affected by the review process
- More fundamental problem is that these investigators are not applying as frequently as represented in the eligible applicant pool
- Awards tend to go to a subset of top-tier institutions
- Some topics do not fare as well in review or otherwise seem to be underrepresented

ACD High-Risk, High-Reward Working Group - recommendations



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Recommendations:

- Enhancing outreach
- New initiatives
- Enhancing diversity

OSC developed a response/implementation plan (approved by NIH leadership, posted on OSC website)

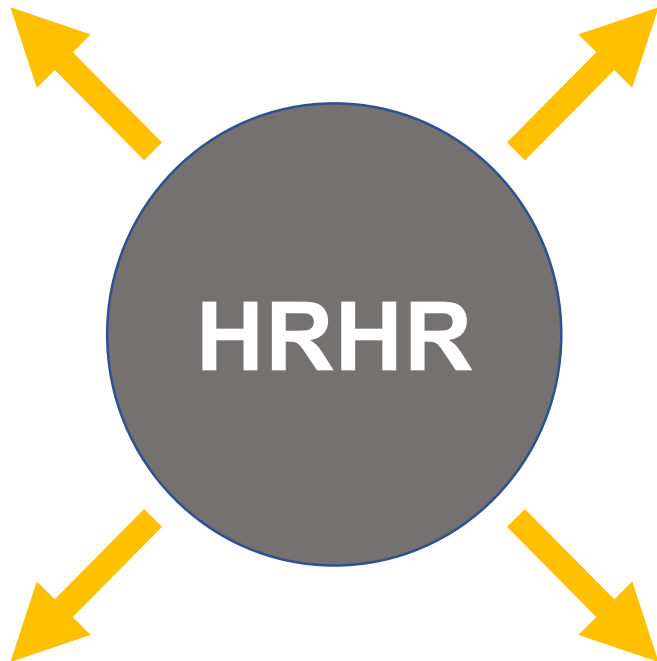
ACD HRHR Working Group - Outreach



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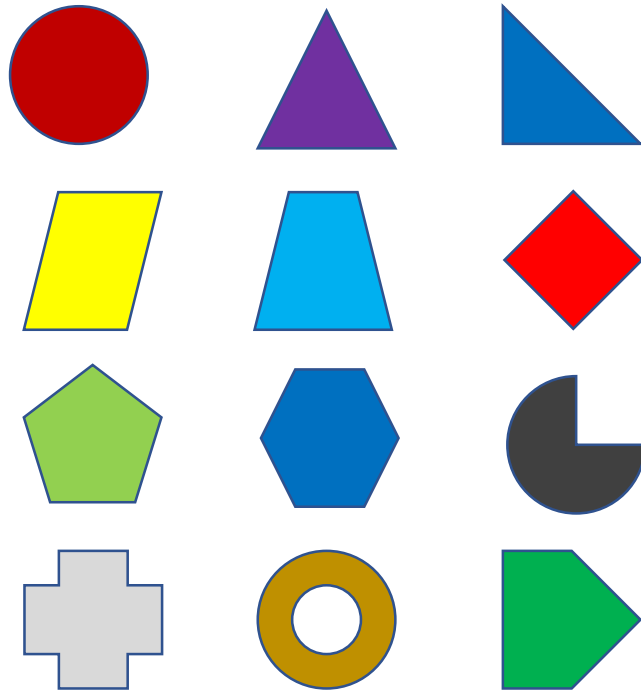


- Conferences focusing on underrepresented groups
- Meetings promoting institutional diversity
- Behavioral and social sciences community
- Online resources
- In addition, issued a Request For Information (NOT-RM-20-002) to solicit input from broad community



Recommendations for new initiatives:

- Collaboration between under-resourced institution and resourced institution (declined)
 - Similar NIH program exists (SCORE)
 - TRA already allows multi-institution applications
- Special track or separate program for clinical outcomes (declined)
 - All HRHR FOAs allow clinical research
 - “High risk” and “no preliminary data” may not be compatible for clinical research, which may be best supported through R01s
 - May be best done at IC level, where definition of “high risk” could be tailored
- Apply New Innovator features to special award for ESIs and expand ESI funding opportunities that do not require preliminary data (accepted)
 - NIH-wide Katz Award is planned for ESIs and will not require preliminary data



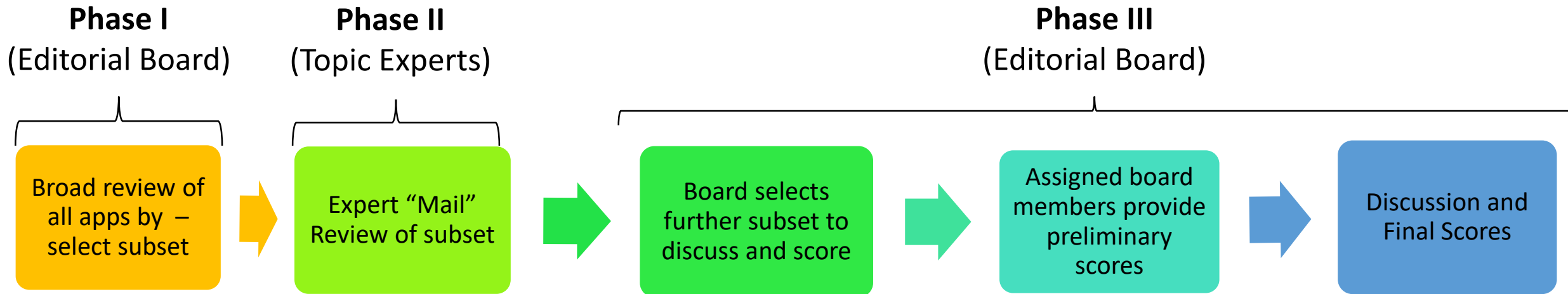
- Make institutional diversity a program priority
 - FOAs will encourage applications from the full spectrum of institutions
 - FOAs will include as a programmatic priority for funding the potential to invigorate HRHR research broadly across the nation
- Take steps to mitigate potential topic bias
 - FOAs will include language explicitly welcoming applications in all topics relevant to broad mission of NIH
 - Outreach efforts will emphasize breadth of potential topics
 - Will work with CSR to ensure appropriate reviewer expertise
- Pilot anonymized review
 - Suggested for Pioneer and Early Independence Awards
 - Will try with TRA, which may be more suitable as a test case

Transformative Research Award – anonymized review



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Current Review Process



Currently, board members and technical reviewers have access to all components of the applications.

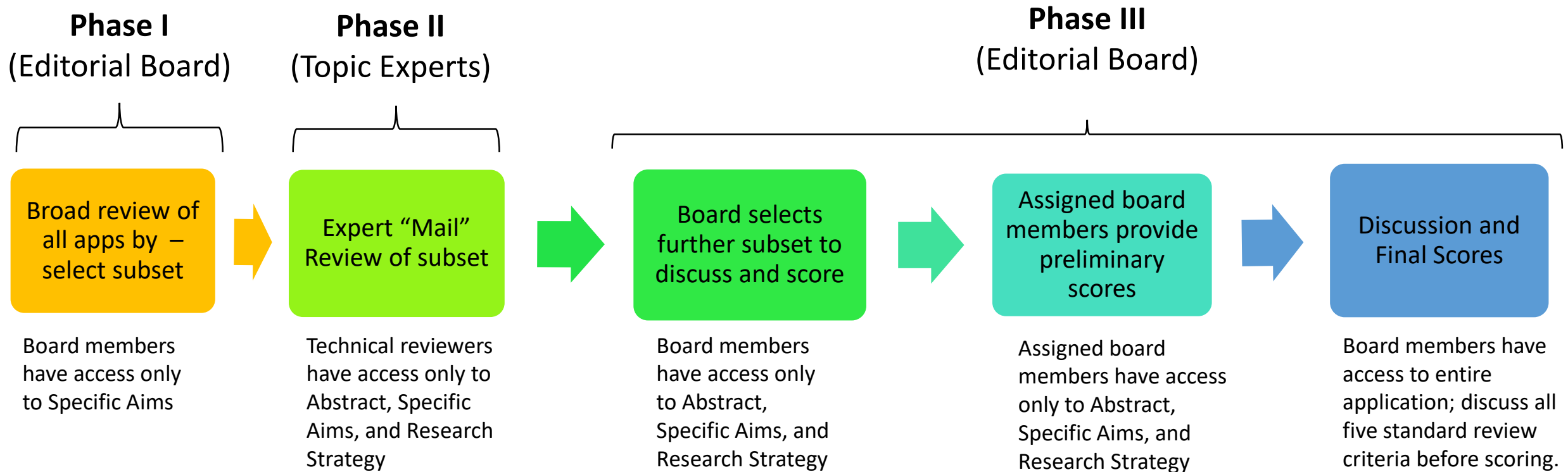
Transformative Research Award – anonymized review



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Proposed Process for Anonymized Review

Abstract, Specific Aims page, and Research Strategy components are anonymized; PIs instructed to provide no information that will reveal PI or institution identity.



Discussion

Council motion and vote to renew the HRHR program through reissue of the HRHR FOAs.

Supplemental slides providing new language in FOAs



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- All HRHR FOAs for FY2021 will contain the following language to encourage applications from a broader set of institutions:

As outstanding research is conducted at a broad spectrum of institutions, it benefits the national scientific enterprise to support exceptionally innovative and impactful science that represents this breadth. Therefore, this Funding Opportunity Announcement encourages applications from the full range of eligible institutions, including those serving primarily underrepresented groups, those that may be less research-intensive, and from all domestic geographic locations.

- All HRHR FOAs for FY2021 will include the following language regarding institutional diversity as a programmatic priority for funding:

Potential to invigorate exceptionally innovative and impactful science broadly across the nation.

- FOAs will include the following language for investigator diversity:

In order to support the most innovative and impactful research, the NIH recognizes the need to foster a diverse research workforce across the nation. Applications to this award program should reflect the full diversity of potential PI/PDs, applicant institutions, and research areas relevant to the broad mission of NIH. Talented researchers from diverse backgrounds, including those from underrepresented racial and ethnic groups, persons with disabilities, and women are strongly encouraged to work with their institutions to develop applications for this Funding Opportunity Announcement

- FOAs will include the following language for topic diversity
 - Funding opportunities will include the following language:

Applications are welcome in all research areas broadly relevant to the mission of NIH. These areas include, but are not limited to, the behavioral, medical, natural, social, applied, and formal sciences. Research may be basic, translational, or clinical. The primary requirements are that the research be highly innovative and have the potential for unusually broad impact.