

Renewal of Four High-Risk, High-Reward NOFOs

Presenters:

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OSC (Common Fund) High-Risk, High-Reward Research NOFOs

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)

Concept Clearance: Reissued Funding Opportunities within the High-Risk, High-Reward Research Program

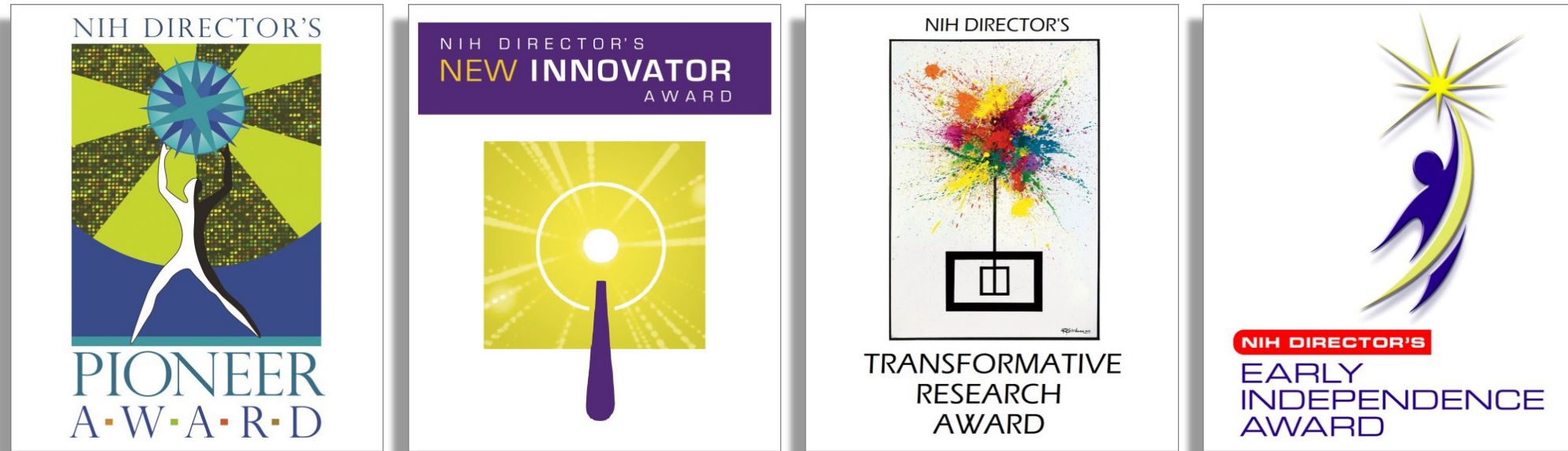
Objective: To foster scientific leaps by supporting individuals of exceptional creativity who propose unusually innovative research with the potential for broad impact, emphasizing the development of the next generation of scientists.

Funds Available and Anticipated Number of Awards: \$59.4M per year (FY26-30); anticipate 50-60 awards/year. For example, in FY26 we anticipate 8 Pioneer Awards, 26 New Innovator Awards, 7 Transformative Research Awards, 13 Early Independence Awards

Award Project Duration: 5 years

Council Action: Vote for approval of the concept for the four NOFOs above

High-Risk, High-Reward Research Program



- Foster scientific leaps
- Any topic within the broad mission of NIH is welcome (“investigator-initiated”)
- No preliminary data or detailed experimental plan required
- Uses non-standard application formats and review processes
- HRHR program not subject to 10-year time limit, individual awards limited 5 years

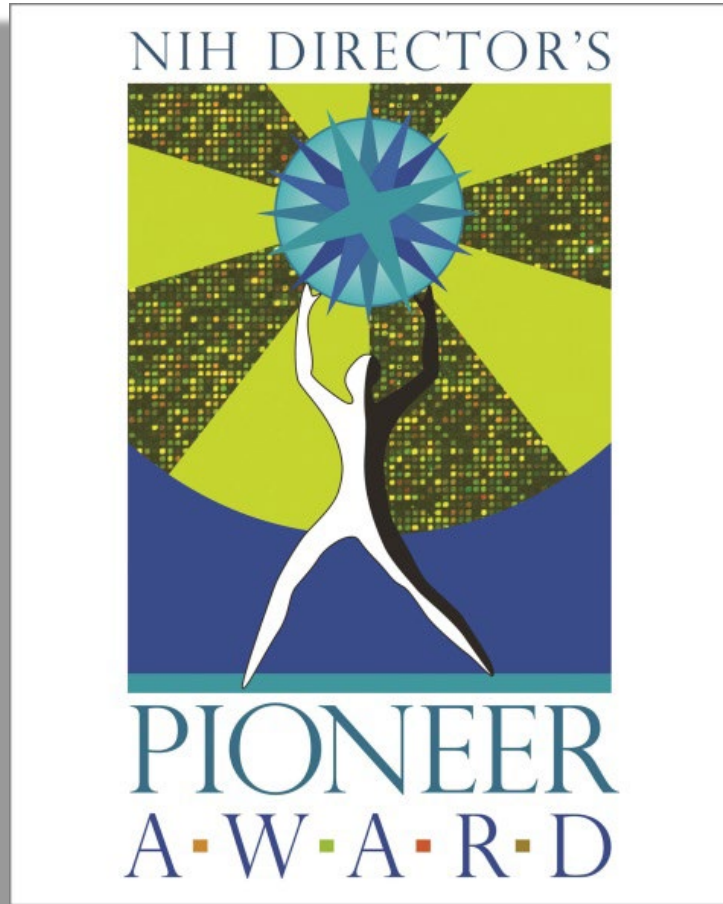
NOFO Goals

A goal of all four High-Risk, High-Reward NOFOs is 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.**

All successful applications will result in bold and highly innovative research.

Additionally, the New Innovator and Early Independence Awards are designed to support promising Early-Stage Investigators (NIH ESI).

NIH Director's Pioneer Award



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**
- **Major portion of research effort** (at least 51%)
- Flexibility to change research direction

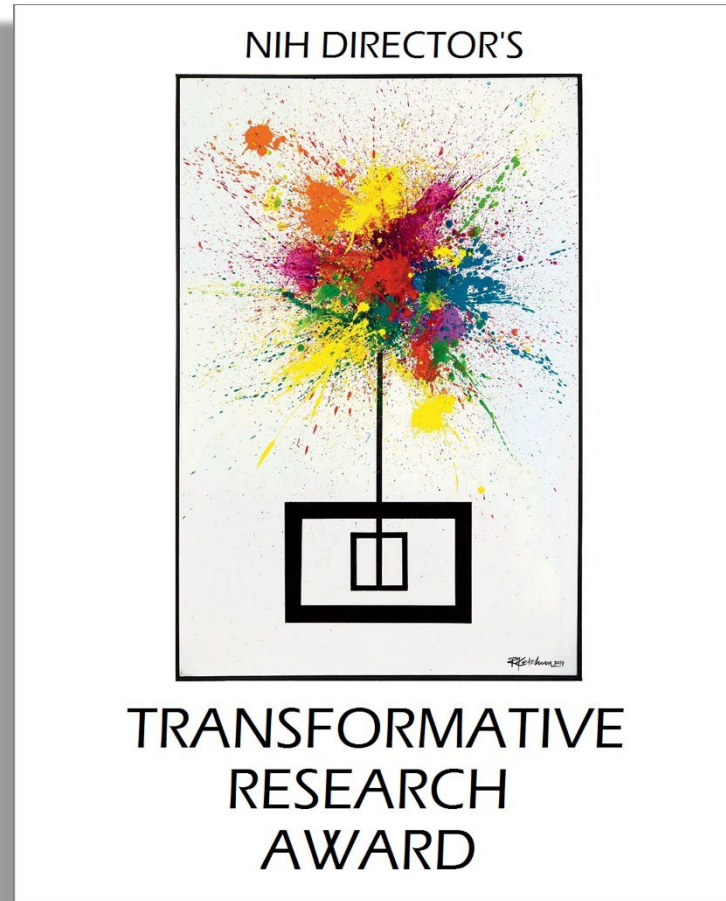
NIH Director's New Innovator Award



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
- Focus on overall idea, innovation, potential impact, innovation history of PI, and suitability of project for New Innovator Award

NIH Director's Transformative Research Award



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
- 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

NIH Director's Early Independence Award



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
- Commit 80% effort to independent research

Anticipated Impact

We expect successful applications to result in bold and highly innovative research across the entire NIH mission.



A Genetic Checkpoint that Could put Alzheimer's Disease to REST

NIH Director's Pioneer Award



Researchers Find New Method to Model Kidney Diseases

NIH Director's New Innovator Award



Researchers Break New Ground Treating Gut Inflammation with Designer Bacteria

NIH Director's Transformative Research Award



Researchers Discover Link Between How Words Sound and Infant Speech Development

NIH Director's Early Independence Award

*Recently highlighted work on website; see <https://commonfund.nih.gov/news-media/science-highlights> for more examples

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Council Action: Vote for approval of High-Risk, High-Reward Research Program NOFOs



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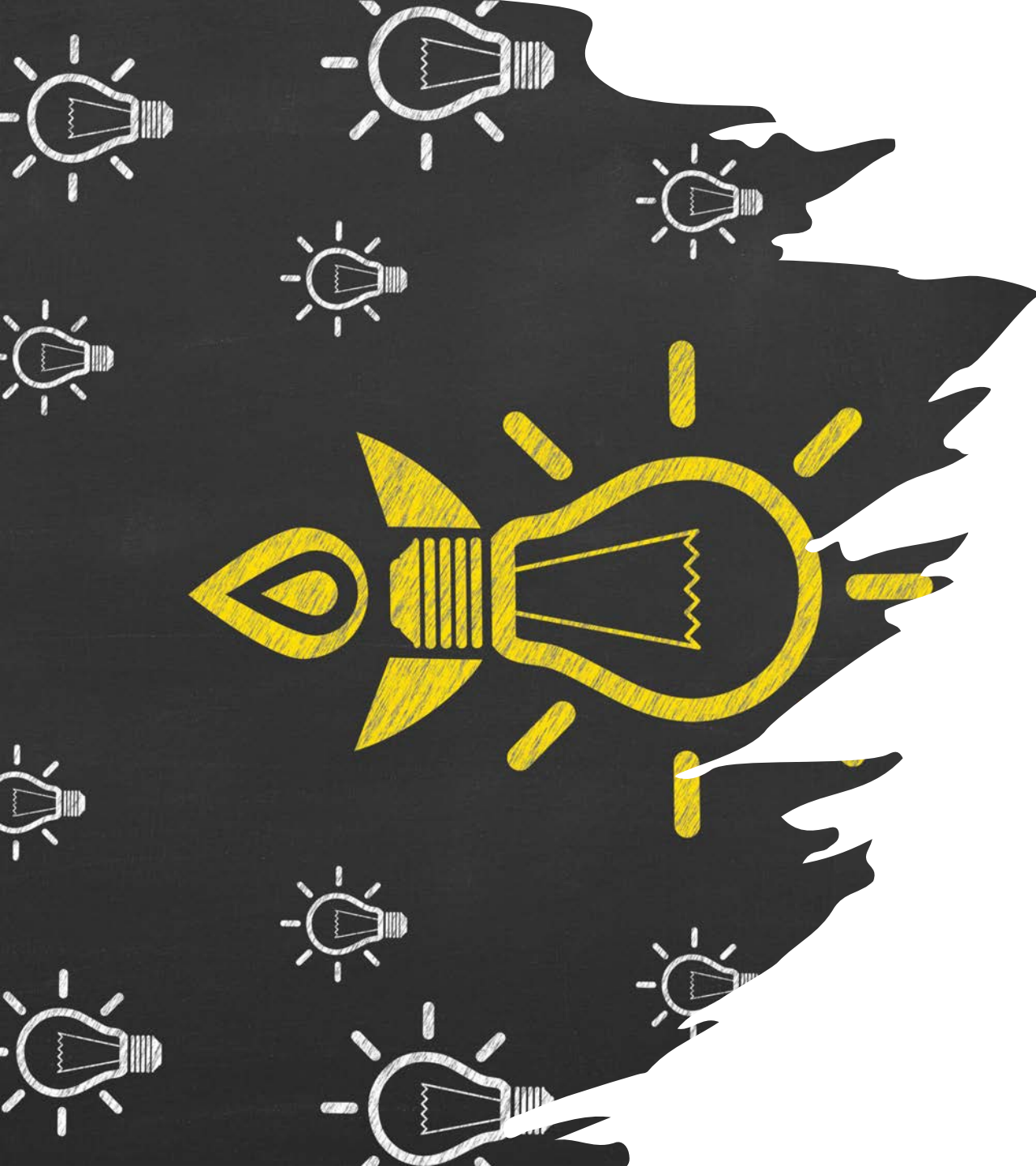
Office of Strategic Coordination–The Common Fund



HRHR Working Group of the Council of Councils

Carolyn Hutter, Ph.D.

Director, Office of Strategic Coordination



Transformational Biomedical Research

- **Characteristics:**

- Innovative research that goes beyond incremental advances
- Creative approaches and substantial breakthroughs that challenge established norms
- Can arise from novel ideas on the “edges” or intersections of disciplines

- **Challenges:**

- Identifying critical topics and approaches with potential impact
- Developing appropriate mechanisms and review processes to foster innovation

Open Questions

- How can we best foster transformative biomedical research at NIH?
- What is the appropriate portfolio balance for HR/HR efforts? How do we assess appropriate risk?
- How do we broaden participation, including across institutions, scientific disciplines and the translational science spectrum?
- What is the leadership role for the Division of Program Coordination, Planning and Strategic Initiatives (DPCPSI) in this space?

