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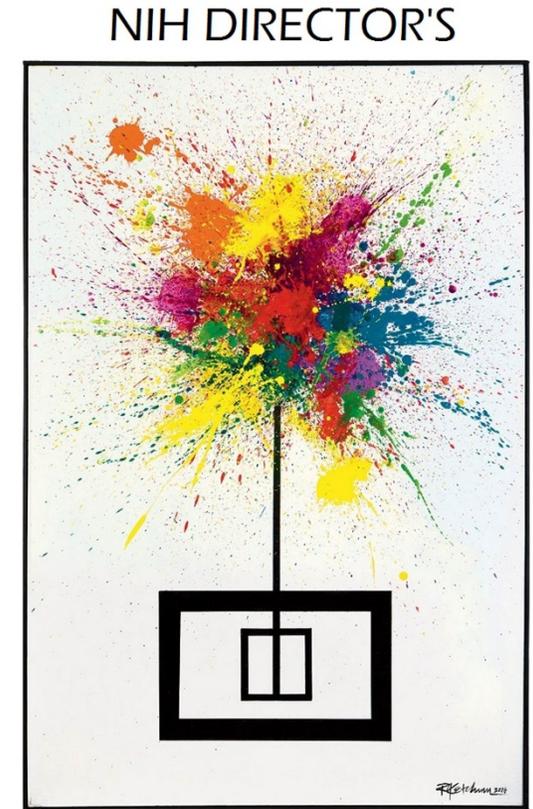
Q&A Webinar

July 24, 2017 @ 3 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



NIH DIRECTOR'S
TRANSFORMATIVE
RESEARCH
AWARD

<https://commonfund.nih.gov/tra>

High-Risk High-Reward Initiatives of the NIH Common Fund

(Common Fund program for “investigator-initiated” HRHR research)



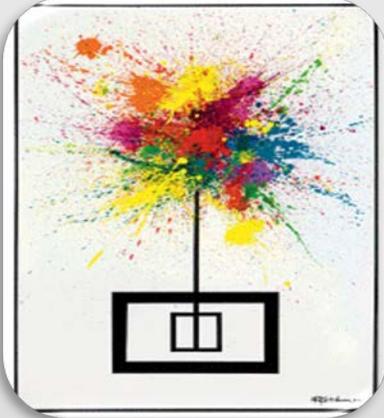
Pioneer Award



New Innovator Award



Early Independence Award

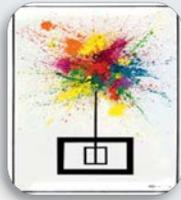


Transformative Research Award

Transformative Research Award Program



- Started in 2009
- Arose from NIH Innovation workshop and Enhancing Peer Review process
- Individuals or teams with a project to overturn or create a fundamental paradigm
- “Outside-the-box” ideas
- Flexible budget



Transformative Research Award Program - implementation

- Application was shorter than standard R01, but now uses standard format
- Application directs individuals to address program specific aspects, such as challenge, impact, innovation, suitability
- Specific Aims page: Not standard format; applicants address Challenge, Innovation, Impact, and Rationale.
- No detailed experimental plan in Research Strategy, but still should be clear to reviewers what it is you want to do and why you want to do it.
- Review process very different from standard R01 review.



NIH Director's Transformative Research Award Review Procedures

2018

**Raymond Jacobson, Ph.D
Chief, Biological Chemistry and Molecular Biophysics IRG
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Review Stages

- Receipt of applications:
September, 2017
- Stage 1: Initial Evaluation by Editorial Board
October-December, 2017
- Stage 2: Mail Reviews for Selected Applications
January-February, 2018
- Stage 3: Discussion&Scoring by Editorial Board
Late March – Early April 2018
- Recommendation by Council of Councils, NIH:
May, 2018

Stage 1 – Initial Editorial Review

- **An Editorial Panel made up of high-level scientists from a wide range of disciplines will be assembled**
- **Editors will evaluate all applications received with particular focus directed towards the Challenge, Innovation, and Impact Statements provided by applicants in lieu of specific aims**
- **4 Editors are assigned to each application and asked to provide a score reflecting the potential for transformative impact on the particular area of science involved.**
- **Applications are selected based on aggregated preliminary scores. Those with the best average scores will be advanced to Stage 2 for further consideration.**
- **Any Editor may rescue any application they feel has transformative potential regardless of preliminary scores.**

Stage 2 Review – Mail Reviews

- **Stage 2 applications selected by the Editorial Panel are distributed by scientific topic area to review staff throughout CSR most familiar with topics involved in each application**
- **Mail reviewers who have appropriate expertise to evaluate each application are identified by the review staff**
- **3 Mail reviewers are assigned to each application.**
- **Mail reviewers provide single page critiques to provide an assessment of the research proposed, qualifications of the team, and the potential for transformative impact**
- **Mail reviewers provide no scores - only an assessment of the science proposed**

Stage 3 Review – Editorial Panel

- Mail reviews collected from Stage 2 are provided to the Editorial Panel
- 4 Editors are assigned to each application and asked to read the application and provided mail reviews
- Each Editor provides a preliminary score reflecting expected transformative impact for assigned applications based on their assessment combined with input from mail reviewers
- Aggregated preliminary scores are used to determine a discussion list typically consisting of the top scoring 50% of the Stage 3 applications.

Scoring and Critiques

- **Stage 1 Applications that do not advance to Stage 2 will not receive a score or scientific critiques, only a description of the review process used**
- **All Stage 2 applications are advanced to Stage 2 – consideration by the Editorial Panel**
- **Stage 3 Applications**
 - **Non-discussed Stage 3 applications receive comments from the 3 mail reviewers. No scores will be provided.**
 - **Discussed Stage 3 applications will receive comments from the 3 mail reviewers, a Resume of the Editorial Panel discussion, and an overall impact score. No criterion scores will be provided**
- **Overall Impact Scores range from 10 (most meritorious) to 90 (least meritorious)**

Editorial Board Review

- **A group of senior researchers will form an Editorial Board to conduct a second stage review.**
- **Each Editor is assigned ~60 applications during Stage 1 and approximately 30 application for Stage 3. Each editor provides preliminary scores at Stage 1 and Stage 3 but provide no written critiques**
- **The Editorial Board will meet in late March/early April to discuss the top ~50% of the Stage 2 applications as determined by the Editor's preliminary scores**

Resources

- **Transformative Research Award Web site**

<https://commonfund.nih.gov/TRA>

- **Request for Application (RFA):**

<https://grants.nih.gov/grants/guide/rfa-files/RFA-RM-17-007.html>

Contact:

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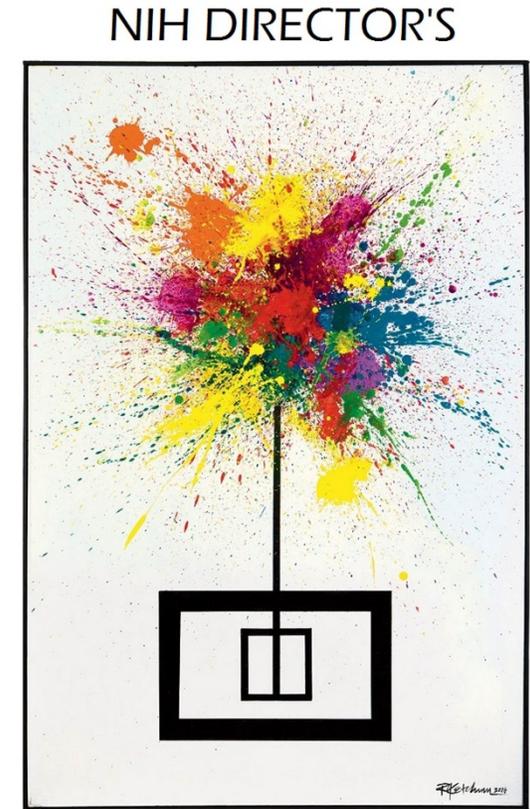
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Questions

July 24, 2017

Eligibility

1. What is meant by a “new and novel research direction” that the NIH Director's Transformative Research Awards are meant to support?
 - A new and novel research direction is one that is distinct from mainstream research currently or previously conducted by the applicant or by other investigators. Successful applicants are expected to conduct innovative studies that challenge current paradigms or establish new paradigms in biomedical or behavioral sciences. It is expected that such studies may be associated with a high level of risk. While a new research direction may have as its foundation the applicant's prior work and expertise, it cannot be an obvious extension of an existing research enterprise. Rather, a new research direction must reflect a fundamental new insight into a problem that may derive from exceptionally innovative approaches and/or from radically unconventional hypotheses.
2. Are multiple PIs allowed to apply?
 - Yes, the Transformative Research Award is the only award in the HRHR program that allows multiple PIs to apply.
3. What issues should be considered when thinking about an application to the NIH Director's Transformative Research Award?
 - Is the topic exciting and interesting? Would someone outside of the field agree?
 - Is the project focused on creating or challenging a central paradigm, developing a broadly useful technology, or creating radical new approaches to disease diagnosis, treatment, or prevention?
 - Is the rationale for the project compelling?
 - If the studies succeed, would there be radical changes in the field?
 - If the studies succeed, would there be a profound impact in other scientific areas?
 - Based on the approach and effort required, will conclusive results be obtained by the end of the project period?
 - Is this really a new idea? Is it substantially different from mainstream research?
4. Are applications proposing clinical research appropriate for this award?
 - Yes, though technical and conceptual risks are expected in highly innovative projects, clinical research also must contend with potential risk to human subjects. Clinical researchers should not be dissuaded from submitting applications as long as rigorous assessment of participant risk/benefit ratios compellingly indicates the ratio to be in favor of the potential benefit. Many of the advances in public health have been achieved through clinical trials, which necessarily involve some risk to participating human subjects. NIH acknowledges the presence of such risk and has established a set of clinical research ethics principles that provides guidance regarding the risk/benefit ratio in clinical research. Applicants proposing clinical research should contact program staff at the appropriate component NIH Institute or Center to ensure that their applications conform to their policies for clinical research.
5. What scientific areas are eligible to apply?

- The NIH encourages applications from scientists from all disciplines, including the biological, behavioral, clinical, social, physical, chemical, computational, engineering, and mathematical sciences, who provide evidence of interest in exploring topics of relevance to the NIH mission. es, it counts as your first significant award.
6. Will technology development be allowed or just hypothesis-driven research?
 - Applications proposing hypothesis-driven research and those proposing the development of new tools and technologies are both encouraged. The focus is on applying highly innovative approaches to create or challenge fundamental scientific paradigms, develop broadly enabling technologies, or create radical new approaches to disease diagnosis, therapy, and prevention.
 7. We are applying from the dental field. Are there any other applications from the dental field that have had success? How competitive are applications from dentistry?
 - Anything relevant to the NIH mission is welcome.
 - Just because something hasn't been funded before does not mean the field isn't welcome.
 - We strive to diversify the program's portfolio when making funding decisions.
 - Focus is on innovation and high impact potential which are unlikely to be funded through traditional NIH mechanisms and reviews. Your application must reflect that.

Application & Submission

1. Can you provide an example application to look at?
 - No, due to privacy concerns we cannot release an example application
 - Due to the innovative and creative nature of the award, it is best to tailor your application to your needs
2. Do I need to submit a Specific Aims page?
 - Yes. However, as indicated in the RFA, this should be used to address the Challenge/Innovation/Impact and Rationale topics and not primarily to list specific objectives of the research.
3. How large should the project be that is being suggested?
4. Is there a penalty for being overambitious?
5. Are citations (references) allowed?
 - Yes, you may include citations in the essay as long as they fit within the ten-page limit. The citations may be in any format.
6. Do I need to include preliminary data in my NIH Director's Transformative Research Award application?
 - No, reviewers will focus on the challenge and approach to judge innovation, novelty, impact and technical merit.
7. Should I include preliminary data if I have any? Or would the presence of preliminary data be counted against the 'innovativeness' of the proposal?
 - Preliminary data may help convince reviewers that the approach is logical and potentially worthwhile. However, be aware that there is no Preliminary Studies section in an NIH Director's Transformative Research Award application. If you have preliminary data, they should be briefly summarized in the Research Strategy section of the application. Also keep in mind that if the preliminary data suggests that success is certain, this may be an indication that the project is not new, exceptionally innovative, or high-risk
8. What is the difference between the Pioneer and Transformative Research Award?

9. What are the program priorities for this specific program? In other words, what research fields are the priority of this program? Will BRAIN research, Aging, Cancer Biology, enable technologies be priorities of the program?

Budget

1. Do I submit a budget?
 - Yes, budgets should be well justified and commensurate with project needs over the project period.
 - Well-justified requests for support of larger research projects may be proposed (up to the amount made available for the entire initiative). Additionally, requests in excess of \$250,000 in direct costs in any year require detailed (non-modular) budgets in addition to compelling justification.
2. What does a budget include?
 - Funds may be requested for personnel (including co-investigators, collaborators, and consultants), supplies, equipment, subcontracts, and other allowable costs. The direct and indirect costs for any subcontract must be included in your direct costs.
3. How much can I ask for?
 - You can ask up to the \$8 million allocated for the entire award. But budget requests must be commiserate with the need of the project and be justifiable.
4. Can the budget include the cost of collecting data abroad (e.g., subject payment, collection, storage, processing and shipment of biosamples), or support collaborators at foreign institutions?
 - Yes, this would be considered foreign components and are allowed. Foreign components are defined by the NIH as the performance of any significant scientific element or segment of a project outside of the United States, either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended. Activities that would meet this definition include, but are not limited to, (1) the involvement of human subjects or animals, (2) extensive foreign travel by recipient project staff for the purpose of data collection, surveying, sampling, and similar activities, or (3) any activity of the recipient that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign country. Examples of other grant-related activities that may be significant are:
 - collaborations with investigators at a foreign site anticipated to result in co-authorship;
 - use of facilities or instrumentation at a foreign site; or
 - receipt of financial support or resources from a foreign entity.
5. Do I need NIH approval before submitting a budget exceeding \$500,000 in annual direct costs?
 - No, because the NIH Director's Transformative Research Award RFA specifies that large budgets may be requested, prior NIH approval will NOT be required for submission of proposals with budgets exceeding \$500,000 in direct costs.
6. How much time/effort are recipients expected to devote?
 - Principal investigators are expected to devote time commensurate to project needs and follow general guidelines as for other NIH projects of similar size, complexity and duration.

7. Is the award transferable if I change institutions?
 - Yes, the award may be transferred to another eligible institution according to the same policies and procedures used for traditional research grants. Awards may not be transferred to foreign institutions.

Review

1. Will the grant application be reviewed by a specific institute, or by a potentially NIH-wide review group/process?
2. Who reviews my application?
3. May I request to exclude a specific reviewer with whom I have a conflict of interest?
4. What will reviewers focus on the most?
5. Will a subject expert review my application?
6. Is it ok to contact previous reviewers to review my grant application prior to submission?
7. Will the applications be reviewed and scored based upon the specific review guidelines and merits using the same or similar score format as all other NIH proposals?
8. Will the final awards be selected based upon the scores, or discretion of program director?
9. Will it be a payline for award selection?
10. In other words, will the applications be handled and reviewed in a fair manner or discretion of program directors?