# Q&A Webinar

July 24, 2017 @ 1 PM EDT

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









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

(Common Fund program for "investigator-initiated" HRHR research)



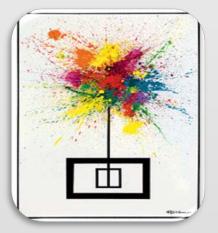
**Pioneer Award** 



**New Innovator Award** 



Early Independence Award



Transformative Research
Award





### **New Innovator Award Program**

- Started in 2007 (in response to concerns that young investigators had difficulty in being funded)
- ➤ Must be <u>Early Career Stage Investigator</u> at time of award (<10 years from Ph.D./clinical residency with no significant NIH support as PI)
- >~\$300K DC/year for five years (Multi-year funded at \$1.5M)
- ➤ Highly innovative research ideas with the potential for broad impact
- Investigators must have track record of exceptional creativity and have outstanding promise





### New Innovator Awards program implementation:

- Application: format designed to focus on innovation, potential impact, qualities of the investigator.
- No specific aims page
- Major component is a 10 page essay; description of project (approach, significance, potential impact), innovativeness of project, investigator qualifications, suitability of the project for New Innovator Award program, statement of 25% research effort commitment.
- Though "R01-level" of experimental detail is not expected, reviewers should still have a clear sense of what it is you want to do and why.
- Preliminary data allowed but not required.
- Review process is non-standard, focuses on significance/potential impact, innovation, investigator qualities.



## 2017-18 Webinar

July 24, 2017

Srikanth Ranganathan, Ph.D. Rajiv Kumar, Ph.D.

# NIH Director's New Innovator Award Program Details

- ✓ Launched in 2007: About 40 awards made every year
- ✓ Open to exceptionally creative Early Stage Investigators (ESI)
- ✓ Goal is to fund bold and highly innovative research with potential to have significant impact in a broad area of biomedical or behavioral research
- ✓ Up to \$1.5 million in direct costs over 5 years

# **Review Stages**

- All applications are reviewed in one panel by 2 stage editorial style review
- First stage mail review focusing on scientific and technical merits
- Second Stage Editorial-style panel review focusing on Overall Impact of applications, with the emphasis on top ~20-25 percent most competitive applications
- Editorial Board Review meeting for final scoring
- Selection of awardees by Office of the Director, NIH
- Public announcement of awardees

## Peer-Review Process – Pre-Stage 1

> Administrative Review: Check for completeness and ESI Eligibility

Applications are grouped based on science areas as identified by the applicant

> Enter conflicts: Institutional / Collaborators from cover letters

> Recruit mail reviewers to cover all major science areas

## **Stage 1 – Mail Reviewers**

- Applicants designate 2 scientific areas out of 9 broad primary and secondary areas
- Reviewers are also asked to designate their primary and secondary areas of scientific expertise
- Match the scientific expertise of reviewers with the science proposed in the application (not just the science areas identified by the applicants)
- Each application is evaluated and scored by 3 mail reviewers on the basis of -
  - "Importance and Potential Impact of the Scientific Problem"
  - "Novelty / Innovativeness of Approach"
  - "Creative Potential of ESI"
- An overall impact score and impact statement is also provided by the mail reviewers

## Stage 2 – Editorial Panel

- Experts with broad scientific understanding are recruited as editorial board members for the second stage (final) study section meeting
- ☐ Based on the stage 1 scores and critiques, editorial board members select about 20% applications for the second stage of the review process
- ☐ Members get access to mail reviewers critiques
- Evaluate overall impact based on mail reviewers' critiques and their own expertise
- ☐ Provide overall impact score and impact statement
- ☐ All finalist applications are discussed in the final review meeting
- ☐ Final scores are released within 3 business days post-meeting
- ☐ Summary statements for all discussed (2<sup>nd</sup> stage impact statements and resume and summary of discussion) and non-discussed (1<sup>st</sup> stage mail reviewers' critiques) applications are released within 35 days post-meeting

### **Questions?**

### Contact:

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#### New Innovator Award Webinar Questions

July 24, 2017

#### Eligibility

- 1. What is a New and Early Stage Investigator?
  - A "New Investigator" is a Principle Director or Principle Investigator who has not been awarded a substantial competing NIH research grant. An "Early Stage Investigator" is an investigator within 10 years of completing his/her terminal research degree or medical residency. Can individuals at any career stage apply?
- 2. Can I extend my Early Stage Investigator status?
  - Yes, if there has been a lapse in your research during the ten-year period after your terminal research degree or the end of medical residency you can request an extension.
  - In general, the NIH will consider requests to extend the Early Stage Investigator period for reasons that can include medical concerns, disability, family care responsibilities, extended periods of clinical training, natural disasters, and active duty military service.
  - Any such request will be considered on a case-by-case basis.
  - Extensions can take several weeks to process.
- 3. Am I still eligible if I've had a K or F award?
  - See the NIH grants policy website for a list of awards that do not affect your New Investigator status.
  - K and F awards do not affect your New Investigator status.
  - R21s do not affect your New Investigator status
- 4. What is an "independent research position?"
  - A position that automatically confers eligibility, according to the applicant's institutional
    policy, for an investigator to apply for R01 grants with an appropriate commitment of
    facilities to be used for the conduct of the proposed research.
- 5. Are postdocs eligible to apply?
  - Yes, if they have an independent research position by September 1, 2018.
  - Since applications are submitted by an institution on behalf of the principal investigator, the application must be submitted by the institution where you will conduct the research. This can be done in advance of your actual appointment date if the receipt deadline is before that date. You should consult the sponsored research office at your new institution about this.
- 6. Am I still eligible if I am awarded an NIH R01 grant after submitting my NIH Director's New Innovator Award application but before awards are made?
  - No, if you receive an NIH award that removes your New Investigator status before the NIH Director's New Innovator Awards are made, you are no longer eligible for the award.
  - You must maintain your New Investigator status until the New Innovator Award is made.
- 7. Am I still eligible if I'm a New Investigator but have an R01 application pending?
  - Yes, you may apply for a NIH Director's New Innovator Award if you have other grant applications pending.
  - You may not submit the same, or essentially the same, project to more than one program as prohibited by NIH policy.

- If the pending grant is awarded before the NIH Director's New Innovator Award, you are no longer eligible.
- 8. Does the NIH Director's New Innovator Award remove your New Investigator status?
  - Yes, it counts as your first significant award.
- 9. My work primarily fits within the Behavioral and Social Science scientific area. Glancing through NIH RePORTER, I see that projects in this category are among the minority of DP2 awards. The video overview on Youtube indicates that one of the emphases of the review is the "project's suitability for the award." Outside of the criteria of significance of the problem, innovation of the approach, and quality of the investigator, can you please discuss how a Behavioral and Social Science project might be viewed as competitive for the criterion of suitability for the award? AND In reviewing the previous recipients of this award, it appears that the clinical social and behavioral sciences are underrepresented. Is this by design? If not, what efforts can someone in these fields make to ensure that their application is competitive, despite the more applied focus of their work?
  - 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.
  - "Suitability for the award" refers to the applications suitability for a high-risk research
    program rather than a traditional R01 mechanism. We are looking for innovative
    approaches with a high impact potential that are unlikely to be funded through
    traditional NIH mechanisms and reviews, and 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. What is the purpose of designating two Areas of Science?
  - The Area of Science designations are to assist in assigning applications to reviewers.
  - To select the most appropriate science area codes for your application, you should consider whether reviewers who are knowledgeable in one or another Area of Science would be most likely to appreciate the significance of the project, the innovativeness of its approaches, and its potential impact.
- 3. What format should the application be in like a standard grant or more like an essay?
  - Read the funding opportunity carefully for all the instructions needed to complete the application.
  - See the SF424 Application Guide for more information where relevant
  - The 10-page essay in the Research Strategy section is unique and must address the significance and potential impact of the proposal, innovativeness of approaches, how risks and challenges will be addressed, and your qualifications
- 4. I understand that, for the Research Strategy, we need to address the areas of scientific rigor, transparency, and reproducibility. For this DP2 application, which specific section in the research strategy should we address these areas? In the Project Description section?
- 5. How large should the project be that is being suggested?
- 6. Is there a penalty for being overambitious?

- 7. Would the presence of preliminary data be counted against the 'innovativeness' of the proposal?
- 8. For most RFAs that don't require preliminary data, it is still beneficial to the application to include some preliminary data. Is it really possible to get a New Innovator Award without including any preliminary data in the application?
- 9. Is it better to wait to apply until more of my research program has preliminary results to show?
- 10. 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.
- 11. For last year's DP2 FOA (RFA-RM-16-004), a cover letter attachment was required that listed the names and affiliations of significant collaborators for the New Innovator Award project. I did not see this requirement in this year's DP2 FOA. Is a cover letter attachment required for this year's DP2 application?
- 12. Can I submit two applications to this funding opportunity?
  - No
- 13. Should I talk to the program officer at the IC that I currently have funding from about applying for a New Innovator Award?
- 14. Do I need to include collaborators for my application to be successful?
- 15. My question surrounds the timing of when a researcher should apply for the DP2. I am an independent scientist, but I have just started my faculty position. Without significant preliminary data, I may be at a disadvantage when compared to other applicants. I will still qualify as ESI in coming years, so this cycle is not my only opportunity to apply.
- 16. Are investigators in liberal arts colleges encouraged to apply?

#### Budget

- 1. Do I submit a budget justification?
  - No, only total five-year budget should be included. We do not require, and will not accept, budgetary details.
- 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. 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:

- o collaborations with investigators at a foreign site anticipated to result in coauthorship;
- o use of facilities or instrumentation at a foreign site; or
- o receipt of financial support or resources from a foreign entity.
- 4. What does "multi-year" funded mean?
  - All \$1.5 million for the project will be disbursed during the first year of the award.
- 5. Are no-cost extensions allowed for unexpended funds?
  - No, because the New Innovator Award is multi-year funded, all funds must be used within the five-year project period.
- 6. Are NIH Director's New Innovator Awards renewable?
  - No, competing renewal applications for a NIH Director's New Innovator Award will not be allowed. At the end of the five-year project period, awardees are expected to seek support to continue their research through traditional routes, such as an R01.
- 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.
- 8. I am currently in the market for shopping of my instruments for my lab using my startup funding, so I am wondering how should I address this in the facility and resources document? More specifically, one of the principle instrument for my proposed research would be a single-molecule microscope that will be set up in my lab not by the deadline of this award application this year, but very soon after that.

#### Review

- 1. Who reviews my application?
- 2. May I request to exclude a specific reviewer with whom I have a conflict of interest?
- 3. What will reviewers focus on the most?
- 4. For the 'Investigator' review criterion, what constitutes "an ongoing record of accomplishments that have advanced their field(s)"?
- 5. Will a subject expert review my application?
- 6. Is it ok to contact previous New Innovator reviewers to review my grant application prior to submission?
- 7. Is it allowed to send updates (such as accepted manuscripts) relevant for this application after the application is submitted and before the review committee meeting?
- 8. Are re-applicants given different consideration than first-time applicants?