

# Transformative R01 Program

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# The TR01 Program in context: an HRHR Demonstration Project

- Fostering transformation via investigator-initiated projects has been a key goal of the NIH Roadmap High Risk/High Reward Program.
- The Roadmap programs are intended to test new ways of identifying transformative research and new mechanisms of funding.
- The 2006 NIH Reform Act encouraged this type of program development by authorizing the creation of High Risk/High Reward Demonstration Projects.
- The Pioneer and New Innovator Programs represent the first two programs of this type in the Roadmap.

# NIH Director's Pioneer Award

Pioneer Awards are designed to support

- **individual scientists of exceptional creativity** who
- **propose pioneering – and possibly transformative – approaches to major challenges in biomedical and behavioral research....**

To be considered pioneering, the proposed research must reflect

- **ideas substantially different from those already being pursued in the investigator's laboratory or elsewhere...**

Pioneer Awards provide \$500K direct costs per year for 5 years; 65 awards have been made since the program's inception in FY2004.



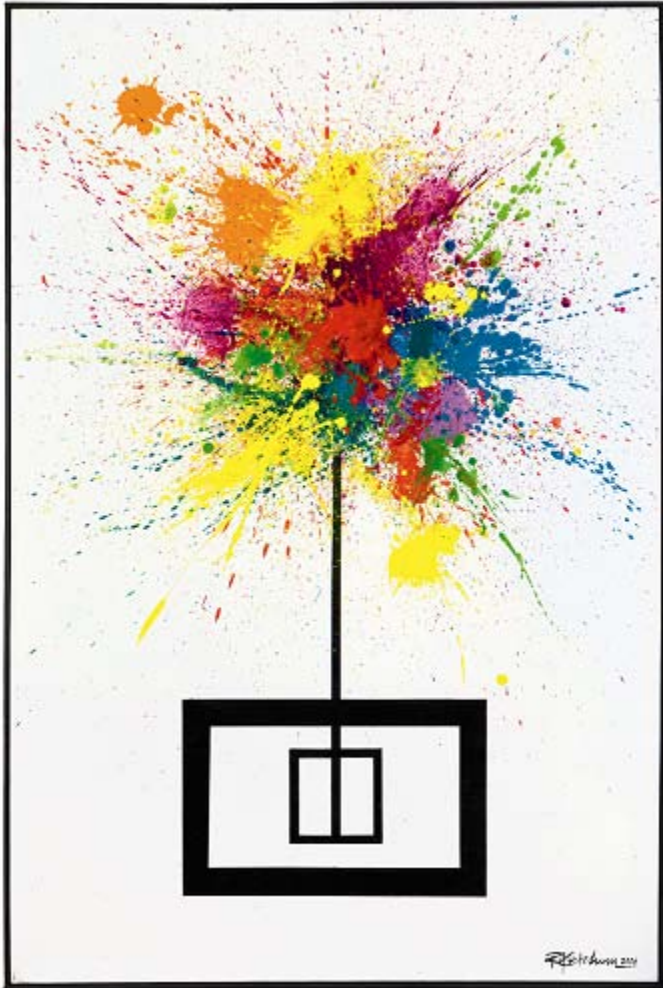
# NIH DIRECTOR'S NEW INNOVATOR AWARD

- Launched in February 2007 with additional resources provided in the 2007 Joint Resolution
- Open to **new investigators** (within 10 years of doctorate)
- Goal is to fund new investigators of exceptional creativity who propose bold and highly innovative new research approaches that have the potential to produce a major impact on broad, important problems in biomedical and behavioral research.
- Up to \$1.5 million direct costs over 5 years
- Funded 31 awards in FY2008

# Pioneer and New Innovator Application and Review

- Pioneer Awards:
  - 2009 competition will proceed in two formal stages, with two separate Funding Opportunity Announcements.
  - Pre-application stage **PAR-09-012** - pre-applications will be assessed by a group of external reviewers
  - Investigators whose proposals are judged to be the most outstanding will be invited to apply through a limited competition RFA - **RFA-RM-09-001** - and will be invited to NIH for interviews
- New Innovator competition will follow similar scheme, although second review will not involve interviews
- Both programs involve a short application with emphasis on prior successes of the applicant as well as impact of the proposed research

# ***Transformative R01 Program***



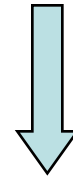
## *Rationale for development:*

Roadmap Cohort 1

Fostering Innovations Workshop (Dec '07)

Enhancing Peer Review

HRHR Demonstration Oversight Group



The NIH needs a program that will allow investigators maximal flexibility to develop “out-of-the-box” transformative projects.

# ***Transformative R01 Program***

## **The Concept:**

- Projects with potential to create or overturn fundamental paradigms
- Inventive, innovative, original and/or unconventional (risk)
- Major impact in biomedical or behavioral research
- Open to all scientific fields of interest to NIH
- Budgetary flexibility allows projects of varying complexities to be supported

# TR01s: a new way to stimulate innovation

- The High Risk/High Reward portfolio within the Common Fund provides different ways of fostering innovation and creativity
  - Pioneer Awards and New Innovator Programs – seek to identify innovative **individuals** and provide them with funds to go in a new direction
  - TR01s – seeks to foster transformative **projects** in any area of health research with minimal oversight by NIH
  - Flexible Research Authority – can be used to support high risk **projects** to reach a defined goal, with NIH maintaining considerable control to ensure milestones toward defined endpoint are met.



# ***Transformative R01 Program***

## **Areas of Highlighted Need:**

- Strategic Planning Process identified areas of particular need:
  - Understanding & facilitating human behavior change
  - Complex 3-dimensional tissue models
  - Functional variation in mitochondria in disease
  - Transitions from acute to chronic pain
  - Formulation of novel protein capture reagents
  - Providing an evidence base for pharmacogenomics
- Program groups can use Roadmap Concept Development Funds to prepare communities for this new program
  - Raise awareness
  - Fostering brainstorming

# ***Transformative R01 Program***

Implementation: **RFA-RM-08-029**

## Important Dates:

- Applications due Jan 29, 2009
- Peer Review (CSR) May/June 2009
- Council Reviews Aug 2009
- Awards Sept 2009

## Investigators:

- extramural only
- multi-PI OK
- any area of NIH research – biomedical or behavioral
- any level

## Funds Available:

- 25M TC FY09
- FOA to be reissued annually for 5 years
- No cost limit per application up to 25M TC

# Transformative R01 Program

Implementation: *RFA-RM-08-029*

## Shorter applications:

- Abstract
  - Biosketch (limited)
  - Research Plan (8 pgs)
  - Lit Cited (1 pg)
- Challenge & Impact (1 pg)
  - Approach (5 pgs)
  - T-R01 Suitability (1 pg)
  - Timeline (1 pg)

## Innovative CSR Review:

- Multi-tiered process using a broad special emphasis panel informed by comments from topic experts
- Emphasis is on significance, innovation & transforming potential

# ***Transformative R01 Program***

## Post-review:

- ICs & program directors assigned
- Second level review by Council of Councils
  - Mandated by the 2006 NIH Reform Act for HRHR Demo Projects
- Funding plan developed by OD & ICs
- NIH Director makes final selection
- Awards September 2009

## Post-award management:

- OSC will convene assigned PDs & GMB to develop consistent mgmt principles
- Annual meeting of awardees

*Awards will begin in FY09, with new competitions planned for FY10, FY11, FY12 and FY13*

# Second level of review by CoC

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- Will be conducted by telephone conference in Summer, 2009.
- Council members will be briefed in advance of the review procedures
- Applications and summary statements will be sent in advance
- Purpose of second level review is to ensure that initial review was conducted with appropriate expertise and lack of conflict