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.
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.
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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.
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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.
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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
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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
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**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
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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

- 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.