Update on “New” Investigator Activities

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• The Research Project Grant (R01) is the original and historically oldest grant mechanism used by NIH.

• The R01 provides support for health-related research and development based on the mission of the NIH.

• R01s can be investigator-initiated or can be in response to a program announcement or request for application.

• The R01 is an award made to support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing the investigator's specific interest and competencies, based on the mission of the NIH.

• The NIH awards R01 grants to organizations of all types (universities, colleges, small businesses, for-profit, foreign and domestic, faith-based, etc.). Although the Project Director/Principal Investigator writes the grant application and is responsible for conducting the research, the applicant is the research organization.
NIH Exceeds New Investigator Goal in FY 2008

NIH First Time R01-Equivalent Awardees
FY 1985-2008

R01-Equivalent awards include R01, R23, R29, and R37 grants.
A Program Director or Principal Investigator (PD/PI) is considered a New Investigator if he/she has not previously competed successfully as a PD/PI for a “significant independent” NIH research grant.

Significant independent NIH research grant: Any NIH research project grant other than the following small or early stage research grants:

- Pathway to Independence Award-Research Phase (R00)
- Small Grant (R03)
- Academic Research Enhancement Award (R15)
- Exploratory/Developmental Grant (R21)
- Clinical Trial Planning Grant (R34)

- Dissertation Award (R36)
- Small Business Technology Transfer Grant-Phase I (R41)
- Small Business Innovation Research Grant-Phase I (R43)
- Shannon Award (R55)
- NIH High Priority, Short-Term Project Award (R56)
Additionally, the PD/PI is considered a "New Investigator" if the only NIH award(s) he/she has received are from the following classes:

- **Training-Related and Mentored Career Awards**
  - Fellowships (F05, F30, F31, F32, F34, F37, F38)
  - Mentored-career awards (K01, K08, K22, K23, K25, K99-R00)
  - Other mentored career awards (developmental K02 as used by NINDS and the developmental K07)
  - Loan repayment contracts (L30, L32, L40, L50, L60)

  Current or past recipients of non-mentored career awards that normally require independent research support (K02, K05, K24, and K26) are **not** considered new investigators.

- **Instrumentation, Construction, Education, or Meeting Awards**
  - G07, G08, G11, G13, G20
  - S10, S15
  - X01, X02
  - R25
  - C06, UC6
  - R13, U13
Setting New Investigator Goals for FY 2009

- Over the past three years, about 25 percent of all competing R01 awards have gone to New Investigators
  - Goals based on rolling average for previous 5 years

- Numeric Goal for FY 2009: 1,650 awards to New Investigators

- ICs are directed to maintain comparable success rates for:
  - Established investigators submitting new (Type 1) grant applications, and New Investigators

- In addition, a majority of New Investigators will be Early Stage Investigators (ESIs)

- Encourage New Investigators to apply for R01s (not R21s or R03s)
NIH created a new ‘Early Stage Investigator’ category designed to accelerate the early transition of new scientists to research independence by receiving their first R01 earlier.

Implementation of ESI Definition

• The NIH modified the collection of information on degree dates and medical residency within the personal profile of the eRA Commons

• PD/PIs must update their personal profile in the eRA Commons in order to be considered for the ESI classification. Investigators who enter degree and residency completion dates will be notified of their ESI status by email.

• A procedure and guidelines for requesting an extension of the period of ESI eligibility was developed and announced to accommodate individuals with various medical concerns, disability, pressing family care responsibilities, or active duty military service (instructions in Commons)

• NIH will eliminate the New Investigator Check Box on the face page of PHS 398 and Form 424 R&R application. New Investigators will be identified using data within the NIH administrative database.
• Applications from ESIs and New Investigators will be identified to reviewers so that appropriate consideration of their career stage can be applied during review.

• An application with more than one Principal Investigator will be identified for consideration by reviewers if all of the listed Principal Investigators qualify as New Investigators.

• Staff in the NIH institutes and centers will be apprised of ESI and New Investigator status and this factor will be considered when applications are selected for award.

• New Investigators will be eligible for the “Full Implementation to Shorten the Review Cycle for New Investigator R01 Applications Reviewed in Center for Scientific Review (CSR) Recurring Study Sections” (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-083.html)
In review, New Investigators applications are interspersed with those from established investigators during the initial peer review process.

- This makes it difficult for reviewers to adequately consider the career stage of the applicant and
- To factor in differences in the availability of preliminary data and other element
The use of Small Grants (R03) and the NIH Exploratory/Developmental Research Grant (R21) has increased in recent years:

New Investigator policies are limited to applications for Traditional Research project grant (R01) support. Accordingly, the NIH is strongly encouraging New Investigators, particularly ESIs, to apply for R01 grants when seeking first-time NIH funding.
Strategies for “Breaking In” to the NIH System

• Understand the NIH process including the review process
• Understand the ICs and their goals
• Get to know your program officers
• Bounce ideas off established investigators
• Look at successful grant applications
• Find Collaborators
• Put forward your best, creative ideas
  – Appropriate number of goals
  – Impact – now more important than ever
  – Preliminary data if you have them.
Other NIH Awards for New Investigators

- Fund exceptionally innovative research with potential for significant impact
- Launched in 2007
  - Open to new investigators within ten years of their terminal degree
  - Appointment at US institutions
  - Commit at least 25% effort
- Up to $1.5 million over 5 years (direct costs)
- Abbreviated application
  - Preliminary data optional
- Review focus on innovation and creativity, scientific impact
- Number of Applications and awards
  - 2007  2150  30
  - 2008  579  31
  - 2009  419  ? + ARRA