

# NIH Grants: New Challenges and Opportunities

# Challenging Times for All Researchers

(NIH funding broken down by institute)

INSTITUTE	NIAMS	NIAID	NCI	NHLBI
SUCCESS RATE FY 2003	20	35	27	34
SUCCESS RATE NFY 2004	20	24	24	29
SUCCESS RATE FY 2005	20	25	20	24
SUCCESS RATE FY 2006	19.3	20.6	19.4	19.7
SUCCESS RATE FY 2007	20.0	23.0	20.1	21.0
SUCCESS RATE FY 2008 (est.)	--	--	--	--
PAYLINE** 2008	14.5	12	14	14

Despite flat nationwide NIH funding, support and number of research grants at New Jersey Medical School have increased markedly

	Total # NIH Research grants	Total NIH research grants
1997	52	\$ 11,426,812
1998	53	\$ 13,012,057
1999	73	\$ 19,554,417
2000	92	\$ 33,343,906
2001	87	\$ 33,558,278
2002	99	\$ 37,309,183
2003	94	\$ 37,462,855
2004	89	\$ 38,392,737
2005	93	\$ 46,964,865
2006	101	\$ 41,552,420
2007	123	\$ 55,451,948

# Grants-NIH

- **R01: good ideas, well-written grant, peer reviewed publications**
- **R03, small grant, usually \$50,000 over two years**
- **R21: The combined budget for direct costs for the two year project period may not exceed \$275,000 (Exploratory/developmental grant support is for new projects only)**
- **STTR/SBIR**
- **Program project grants, center grants**
- **T32: training grants (support for graduate students and postdoctoral fellows)**
- **Shared instrumentation grants (SIG)**

# NIH Roadmap

- New Pathways to Discovery
  - Building Blocks, Biological Pathways, and Networks
  - Molecular Libraries and Imaging
  - Structural Biology
  - Bioinformatics and Computational Biology
  - Nanomedicine
  - Epigenomics
- Research Teams of the Future
- High-Risk Research
  - NIH Director's Pioneer Award
- Interdisciplinary Research
- Public-Private Partnerships
- Re-engineering the Clinical Research Enterprise

# GCRC-CTSA

- General clinical research center (NCRR)
  - Provides infrastructure for clinical research
    - Nursing staff
    - Technicians
    - Dedicated hospital space
- Clinical translational science award (NCRR)
  - this program will encourage the development of novel methods and approaches to clinical and translational research, enhance informatics and technology resources, and improve training and mentoring to ensure that new investigators can navigate the increasingly complex research system.
  - Emphasizes basic research more

# New initiative

- Multiple PI's
- There is growing consensus that team science would be encouraged if more than one PI could be recognized on individual awards. The NIH has adopted a multiple-PI model, as directed by the Office of Science and Technology Policy.

# Multiple Principal Investigator Awards

- Began in Feb 2007 to support “team science” approach
- Option is available with most (not all) grant formats
- Applications must include “Leadership Plan” describing roles of PIs
- Separate budget allocations may be requested
- PIs share responsibility and authority for leading and directing project
- First PI must be affiliated with applicant institution & is contact person for NIH
- All PIs are listed on summary statements, NGAs, and in CRISP
- The term Co-PI is no longer used by the NIH

# Plan for Enhancing Peer Review Process

The NIH initiated a formal review of its review process in June 2007 and identified 3 priority goals:

- 1 - To Engage the Best Reviewers
- 2 - To Improve the Quality and Transparency of Review
- 3 – To Ensure Balanced and Fair Reviews across Scientific Fields and Career Stages and to Reduce Administrative Burden

# Plan for Enhancing Peer Review Process (2008-2010)

- Continuous Submission Process for Study Section Members
- Revised Policies for New and Early Stage Investigators
- New Policy on Resubmissions
- New Scoring Procedures
- Enhanced Review Criteria
- Applications shortened

### Continuous Submission Process for Study Section Members

- Began in February 2008 - to recognize and encourage study section service.
- Applies to PIs who are appointed members of chartered NIH study sections.  
(Does not apply to temporary or ad hoc members of NIH study sections.)
- Applies to R01s, R21s, and R34s due on standard submission dates.  
(Does not apply to grants with special due dates or other activity codes.)
- *Applications can be submitted at any time and will be reviewed within 120 days.*

### • Revised Policies for New and Early Stage Investigators

#### In 2009...

- The NIH will support new<sup>1</sup> and early stage Investigators<sup>2</sup> at R01 success rates comparable to established investigators.
- New Investigator R01 applications will be clustered during review. Peer reviewers will be instructed to focus more on the proposed approach than on the track record, and to expect less preliminary data than would be provided by an established investigator.
- The NIH strongly encourages new investigators to apply for R01 grants when seeking first-time NIH funding.

*1. New Investigator: one who has not successfully applied for significant NIH funding*

*2. Early Stage Investigator: a new investigator who is within 10 years of completing his/her terminal degree or medical residency*

# Plan for Enhancing Peer Review Process

*In 2009...*

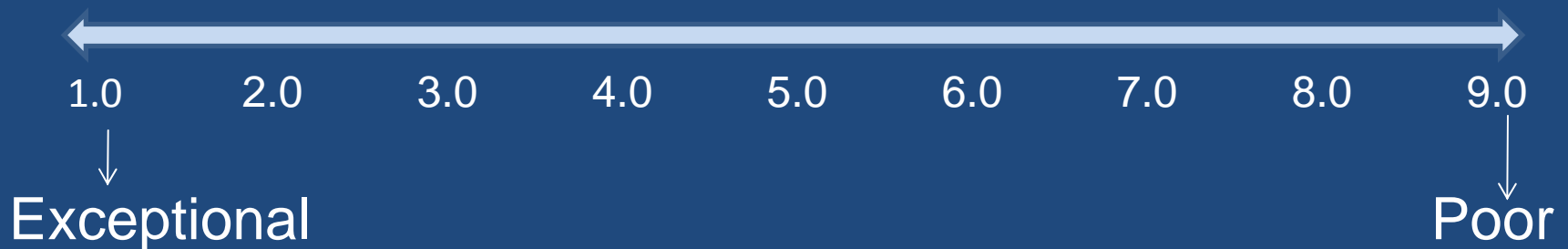
## New Policies on Resubmissions

- Only **one amendment** to an original application will be accepted.

## New Scoring Procedures

- Pilots will be conducted on the feasibility of using high-bandwidth support for review meetings to provide reviewers an alternative to in-person meetings.
- The use of a new criteria-based 9-point scoring system and formatted reviewer critiques will commence.
- Streamlined applications will receive a preliminary score.

## New Scoring System



Scores are rated from 1 – 9 in .1 increments.

# New Scoring System

1. Before the review meeting, each application will be given a separate score by each reviewer for **Preliminary Impact** and for each criteria.

These scores will be reported on the summary statement, including applications not considered for funding.

2. **Preliminary Impact** scores will be used to determine which applications will be considered for funding.

3. At the review meeting, each application considered for funding will be given a separate score by each reviewer for **Final Impact**.

4. The mean of all the reviewer's **Final Impact** scores X 10 =  
The **Overall Impact** score.

81 possible scores ranging from 10 – 90.

## Enhanced Review Criteria

Core Review Criteria (always scored):

- *Significance*
- *Investigator(s)*
- *Innovation*
- *Approach*
- *Environment*

## Enhanced Review Criteria

Core Review Criteria (always scored):

• *Significance* →

Does the project address an important problem or a critical barrier to progress in the field?

• *Investigator(s)*

• *Innovation*

If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?

• *Approach*

How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

• *Environment*

## Enhanced Review Criteria

Core Review Criteria (always scored):

• *Significance*

Are the PD/PIs, collaborators, and other researchers well suited to the project?

• *Investigator(s)* →

If Early Stage Investigators or New Investigators, do they have appropriate experience and training?

• *Innovation*

• *Approach*

If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)?

• *Environment*

If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

## Enhanced Review Criteria

Core Review Criteria (always scored):

• *Significance*

• *Investigator(s)*

• *Innovation*

• *Approach*

• *Environment*

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?

Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense?

Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

## Enhanced Review Criteria

Core Review Criteria (always scored):

• *Significance*

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?

• *Investigator(s)*

• *Innovation*

Are potential problems, alternative strategies, and benchmarks for success presented?

• *Approach* →

If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

• *Environment*

If the project involves clinical research, are the plans for protection of human subjects, and inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

## Enhanced Review Criteria

Core Review Criteria (always scored):

- *Significance*

Will the scientific environment in which the work will be done contribute to the probability of success?

- *Investigator(s)*

Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed?

- *Innovation*

- *Approach*

- *Environment*



Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

## Enhanced Review Criteria

Additional Criteria (scored when applicable):

- Protection for Human Subjects
- Inclusion of Women, Minorities, and Children
- Vertebrate Animals
- Resubmissions
- Renewals
- Revisions
- Biohazards

# Plan for Enhancing Peer Review Process

In 2010...

- R01 applications will be reduced in length (12 page research plan).
- Applications will be restructured to align with new review criteria.

# Plan for Enhancing Peer Review Process

Updated Implementation Deadline (Dec. 2, 2008)

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**January 2009 Due Dates** (for potential FY2010 funding)

- Early Stage Investigator (ESI) and New Investigator Policy
- New NIH Policy on Resubmissions

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**May 2009 Review Meetings** (for potential FY2010 funding)

- 9-Point Scoring System
- Enhanced Review Criteria
- Formatted Reviewer Critiques
- Scoring of Individual Review Criteria
- Clustering of New Investigator Applications During Review

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**January 2010 Due Dates** (for potential FY2011 funding)

- Shorter Applications for R01s and Other Mechanisms
  - Restructured Applications to Align with Review Criteria
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Good Luck!