Report on Enhancing Peer Review at NIH Implementation Plan

96th Meeting of the Advisory Committee to the Director

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June 6th, 2008
Reviewing and Improving
Peer Review at NIH

- Reality: First-rate peer review is a cornerstone of NIH
- Emerging Reality: Increasing breadth, complexity, interdisciplinary nature of biomedical science are creating new challenges for peer review
- Funding trends aggravate the stress on peer review
- NIH Response: Reviewing – and enhancing – peer review

The Continuing Charge:
“Fund the best science, by the best scientists, with the least administrative burden…”

And the Added Challenge:
… but recognize that “best” is dependent on many factors including: scientific quality; public health impact; mission of Institute or Center; existing NIH portfolio
Enhancing Peer Review

Diagnostic

Jul 07 - Feb 08

- Request For Information
- 2 Deans Teleconferences
- ACD & SC Working Groups
- 5 Regional Meetings
- National Advisory Councils
- NIH Functional Committees
- Scientific Liaisons
- NIH Staff

Draft Recommendations Report
Feb 29, 2008

Design Implementation Plan
Mar 08 - June 08

- NIH Staff & Public Comment
- SC Peer Review Implementation Groups
- Position Papers from NIH Functional Committees
- SRO/NIH Staff Town Hall Meeting
- SC Peer Review Cross Cutting Committee

Begin Phased Implementation of Selected Actions
June 08

- Advisory Committee to the Director
- Study Section Chairs
- NIH Functional Committees
- IC Directors
- Steering Committee
- Peer Review Advisory Committee

Draft Implementation Plan
Apr 15, 2008

Input on Draft Recommendations Report
Granularity of the Discussion:

We need to tackle the big challenges

Guided by several principles:

1. Do no harm
2. Continue to maximize the freedom of scientists to explore
3. Focus on the changes that are most likely to add significant value at a reasonable cost/benefit ratio
Four Core Priorities Emerged

1. Engage the best reviewers
2. Improve the quality and transparency of reviews
3. Ensure balanced and fair reviews across scientific fields and scientific career stages and reduce burden on applicants
4. Develop a permanent process for continuous review of peer review
Priority 1: Engage the Best Reviewers

- The excellence of peer review is directly correlated to our ability to recruit and retain the most accomplished, broad-thinking and creative scientists to serve on study sections.

Academic Rank of All CSR Reviewers

- Professor
- Associate Professor
- Assistant Professor
Priority 1: Engage the Best Reviewers

Goal 1: Increase flexibility of service to better accommodate reviewers
  - Spread 12 session reviewer commitment over 4-6 years
    - Allow duty-sharing by colleagues as appropriate
  - Expand use of flexible submission deadlines
  - Pilot and evaluate new forms of high bandwidth electronic review
Priority 1: Engage the Best Reviewers

Goal 2: Recruit additional accomplished reviewers to serve on study section

- Enhance recruitment strategies to attract a greater number of accomplished extramural and intramural investigators to serve as reviewers
- Establish a policy that certain classes of NIH grant awards would include a service expectation for PIs, including:
  - Honorific awards: Merit/Javits, Pioneer
  - Grants where the PI is named as PI on three or more additional R01 equivalents
  - Type 2 renewals with >$500K direct costs
Priority 1: Engage the Best Reviewers

- Goal 3: More formally acknowledge the efforts of all reviewers
- Goal 4: Make the review experience intellectually more rewarding
  - Focus the discussion on impact and innovation/originality of proposals
  - Ranking proposals at the meeting’s conclusion will provide feedback to the study section members
  - Study sections will be engaged directly in the piloting of many of the interventions
Priority 1: Engage the Best Reviewers

- **Goal 5:** Compensate the time and effort required for outstanding and sustained service for those reviewers who serve for a minimum of 18 full study section meetings as chartered members or equivalent service
  - Individuals may apply for an administrative supplement of up to $250K (TC)
  - Individuals may request that they be considered for Merit/Javits awards on a competitive basis

- **Goal 6:** Enhance review quality by providing additional training and mentoring to all study section chairs, reviewers and Scientific Review Officers
  - Develop an NIH-wide standardized core curriculum based on best practices augmented by IC and study section-specific additions
Priority 2: Improve the Quality and Transparency of Reviews

- Peer review must consistently identify an application’s relative merit, potential for scientific and/or public health impact, and feasibility

- The reliability of individual rating scales is a monotonically increasing function of the number of steps

- As the number of scale steps increases from 2 to 20, the increase in reliability is very rapid at first, but tends to level off at about 7

- A seven scale steps provides appropriate balance between scale reliability and discriminative demand on the respondent

  (Nunnally, 1978)
Goal 1: Modify the rating system to focus on specific review criteria, with less emphasis on methodological details and more emphasis on potential scientific impact

- Assigned reviewers will provide individual scores for each of five review criteria (1→7) and a preliminary global score
  - 5 specific review criteria: impact, investigator(s), innovation/originality, project plan/feasibility and environment
Priority 2: Improve the Quality and Transparency of Reviews

- Goal 1: Modify the rating system to focus on specific review criteria, with less emphasis on methodological details and more emphasis on potential scientific impact (continued)
  - For applications that are not streamlined:
    - All study section members, based on a discussion of each criterion, will provide a global score (1→7)
    - After initial scoring, all proposals within relevant categories will be discussed as a group and ranked in some manner
      - Ranking at the conclusion of meeting allows for “recalibration” of global scores
    - To provide all applicants with specific feedback, applications that are streamlined will receive five scores - one for each criterion, representing the average from all reviewers
Goal 2: Restructure the summary statement to align with the explicit rating criteria

- Develop and use a summary statement template with a separate field and prescribed amount of space for each criterion
- Provide an optional field for reviewers who wish to provide applicants with additional advice (“mentoring”) including the opinion that the proposal should not be resubmitted unless fundamentally revised as a new application
- Develop appropriate tools, guidance and training for reviewers for best practices for generating summary statements
Priority 2: Improve the Quality and Transparency of Reviews

- Goal 3: Shorten and redesign applications to align with the NIH review criteria starting with R01, R15, R21, R03, K, and F applications
  - Twelve pages for R01s, with other mechanisms to be scaled appropriately
  - Structure of application will align with explicit review criteria
  - The use of an appendix of up to 8 pages will be permitted, but only for specific information that is deemed critical on the basis of NIH-defined criteria (e.g., elements for a clinical trial or a large epidemiologic study)
Priority 3: Ensure Balanced and Fair Reviews Across Scientific Fields and Career Stages

- Peer review should fairly evaluate proposals from all scientists, regardless of their career stage or discipline, and avoid bias towards more conservative and proven approaches at the expense of innovation and originality.

- It should not disadvantage early stage investigators.

- It should apply the appropriate weighting of past performance and future potential for impact as a function of career stage and productivity.

- It should be designed to minimize the need for repeated or multiple applications from meritorious scientists to achieve funding support.

- It should encourage “transformative” research.
Age Distribution of NIH RPG Investigators: 1980

Average Age
New R01 Investigator: 37.2

Sources: IMPAC II Current and History Files
Age Distribution of NIH RPG Investigators: 2006

Sources: IMPAC II Current and History Files

Average Age
New R01 Investigator: 42.2
Preliminary Projection of Age Distribution of NIH RPG Investigators: 2020

Sources: IMPAC II Current and History Files and Preliminary Demographic Projection Model
Impact of Budget Growth on Number of New R01 Investigators

Number New R01 Investigators

Budget Growth

New Investigators

Budget Growth (Percent)

New NIH Policy

1983 1985 1987 1989 1991 1993 1995 1997 1999 2001 2003 2005 2007
Number of Scored Applications from First-time Investigators are Dropping

-535 Applications

+339 Applications

Number of Scored New (Type I) R01 Applications

<table>
<thead>
<tr>
<th>Year</th>
<th>From Established Investigators</th>
<th>From First-time Investigators</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
<td>10000</td>
<td>4000</td>
</tr>
<tr>
<td>2007</td>
<td>10000</td>
<td>439</td>
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Priority 3: Ensure Balanced and Fair Reviews Across Scientific Fields and Career Stages

- **Goal 1:** Continue to support and develop policies to fund a minimum number of early stage investigators (ESI) and new (to NIH) investigators, as appropriate
  - Cluster review, discussion, scoring and ranking of ESI within a study section
  - Pilot percentiling ESI across all study sections
  - NIH will work to ensure that the number of fully discussed proposals from ESI is not disproportionately reduced

- **Goal 2:** For more experienced investigators, place equal emphasis on a retrospective assessment of accomplishments and a prospective assessment of what is being proposed

- **Goal 3:** Cluster the review, discussion, scoring and ranking of clinical research applications within a study section
Goal 4: Encourage and expand upon the Pioneer, EUREKA and New Innovator awards review experience to encourage risk taking by applicants

- Applicants propose ideas with “transformative” potential as main criterion in concert with a prospective evaluation to measure effectiveness of this approach

- Continue to grow the Transformative Research portfolio to reach to ~1% of R01-like awards
  - Pioneer and New Innovator Award: $550M over 5 years
  - EUREKA Award: $200M over 5 years
  - New, investigator-initiated “transformative” R01 pathway using the NIH Roadmap authority and funding: $250M over 5 years
Priority 3: Ensure Balanced and Fair Reviews Across Scientific Fields and Career Stages:
Reducing Burden on Applicants, Reviewers and NIH staff

Goal 5: Based on analysis of success rates as a function of initial scores, reduce the need for resubmissions
- Reduce the rate of resubmissions from applicants with high likelihood of funding based on A0 review
- Reduce the rate of resubmissions for applicants with very low or no likelihood of funding based on A0 review
- Establish policies to carefully rebalance success rates among A0, A1 and A2 submissions to increase system efficiency
- Share relevant review and funding data with all applicants (statistics on cumulative success rates as a function of score or percentile will be made part of summary statement)
Percent R01-equivalent Awards and Amendment Status
# Change in the Number of Unsolicited Type 1 R01 Applications, Awards by Amendment Status

<table>
<thead>
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<th>Year of Original (A0) Submission</th>
<th>1998</th>
<th>1999</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
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<td>11214</td>
<td>11245</td>
<td>10713</td>
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<tr>
<td>Actual A0 Awards</td>
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<td>1853</td>
<td>1827</td>
<td>1714</td>
<td>1574</td>
<td>1225</td>
<td>945</td>
</tr>
<tr>
<td>Actual A0 % Paid</td>
<td>18%</td>
<td>19%</td>
<td>18%</td>
<td>17%</td>
<td>17%</td>
<td>14%</td>
<td>11%</td>
<td>9%</td>
<td>7%</td>
</tr>
<tr>
<td>Actual A1 Apps</td>
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<td>3972</td>
<td>4015</td>
<td>3993</td>
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<tr>
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<td>1291</td>
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<td>1525</td>
<td>1462</td>
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<tr>
<td>Actual A1 % Paid</td>
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<td>31%</td>
<td>32%</td>
<td>32%</td>
<td>31%</td>
<td>28%</td>
<td>24%</td>
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<td>22%</td>
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<td>465</td>
<td>506</td>
<td>492</td>
<td>573</td>
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<td>912</td>
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<tr>
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<td>43%</td>
<td>47%</td>
<td>46%</td>
<td>42%</td>
<td>38%</td>
<td>41%</td>
<td>44%</td>
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Improvement in Median A1 to A2 Priority Score

Median Change from A1 to A2 Priority Score
by Year of Original Submission (A0)
for Unsolicited Type 1 R01 Applications

Change from A1 to A2
(negative values reflect better scores on A2)

A1 Priority Score

-90 -80 -70 -60 -50 -40 -30 -20 -10 0

175 200 225 250 275

1998
2000
2002
2004
2006
Number of Type 1 R01 Applications Required for Funding

By Percentile of Original A0

2006 Applications/award

1998 Applications/award

Almost twice as many rounds of application required today . . .

Though most are still ultimately funded

81% ultimately funded

96% ultimately funded

Avg Applications Required

A0 Percentile

5 10 15 20 25 30 35 40 45 50 55 60 65 70 75
Priority 4: Develop a Permanent Process for Continuous Review of Peer Review

- The NIH peer review process should commit itself to a continuous quality control and improvement process based on a more rigorous and independent prospective evaluation that favor rather than discourage adaptive and innovative approaches to review and program management.

- Pilot and evaluate new models of review
  - 2 stage reviews (editorial board models)
    - The use of “prebuttals”
  - Pilot and evaluate different methods for ranking relative merit of applications
  - Pilot and evaluate high bandwidth electronic review
  - Develop metrics for monitoring performance of review
Consideration of Salary Support and Percent Effort
Two-thirds of NIH principal investigators have 50% or less in aggregate percent effort.
Minimum Percent Effort

- Unintended consequences related to different business models used by applicant organizations

**Alternative proposal**: Include a subfield in the “Environment” section of the application where applicants must indicate if they have (or project having) NIH RPG support in excess of $1M (at the time when the current application would be funded)

- In such cases the applicant must justify why additional resources are being requested at this time
Next Steps

- Ad hoc Peer Review Task Force, chaired by NIH Deputy Director, will be formed to develop detailed plans and oversee initial implementation.
- New entity to be formed within the Division of Program Coordination, Planning and Strategic Initiatives to oversee Continuous Review of Peer Review.
Reviewing Peer Review: Project Phases

- Diagnostic
  - Jul 07 - Feb 08

- Design Implementation Plan
  - Mar 08 - June 08

- Begin Phased Implementation of Selected Actions
  - June 08

- Implement Communication Plan with Stakeholders

- Evaluate Actions

- Develop New NIH Policies
Thank you

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