



Peer Review: a Research Priority

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Objectives of Grant Peer Review

- Maintain standards of scientific rigor and integrity
- Provide unbiased review
- Identify the most meritorious proposals
- Identify those proposals most likely to fulfill PCORI's research priorities and agenda
 - Incorporate perspectives of patients, health care providers, and other stakeholders

Empirical Studies of the Characteristics of Peer Review

- **Reliability**
 - Is concordance among reviewers the goal?
 - Small number of focused reviewers vs. larger number with different backgrounds
 - Reliability does not necessarily equate with validity
- **Validity**
 - How evaluate?
 - Research need: criteria for evaluating predictive validity on the “quality” of funded research
- **Fairness**
 - > 25 potential sources of bias identified
 - Inconsistent results among studies
 - Statistical models developed to adjust for bias

Review Outcomes of R01 Applications

	1994			2004	
	HS+ (n=4,128)	HS- (n=10,749)		HS+ (n=5,813)	HS- (n=10,652)
% unscored	10.8%	6.8%*		43.7%	37.2%*
Median Priority	232	205*		264	234*
% Apps ≤20% ile	17.7%	21.7%*		17.7%	21.8%*
% Funded	17.8%	22.0%*		18.3%	23.5%*

* p< 0.001

Success Rates of Grant Applications Reviewed in the Institutes and Centers is Greater than those Reviewed in the Center for Scientific Review
R01 and Equivalent Grants (FY 2005)

R01 Equiv.

R01 Equivalent Applications

28,423
Applications
10,199 HS+
(36%)
18,224 HS-
(64%)

Locus of Review

CSR

26,243
Applications
8,687 HS+
(33%)
17,556 HS-
(67%)

IC

2,180
Applications
1,512 HS+
(69%)
668 HS- (31%)

Awards

HS+
1,627 Awards
Success Rate
19%

HS-
4,298 Awards
Success Rate
24%

HS+
298 Awards
Success Rate
20%

HS-
240 Awards
Success Rate
36%

Dear
Applicant,



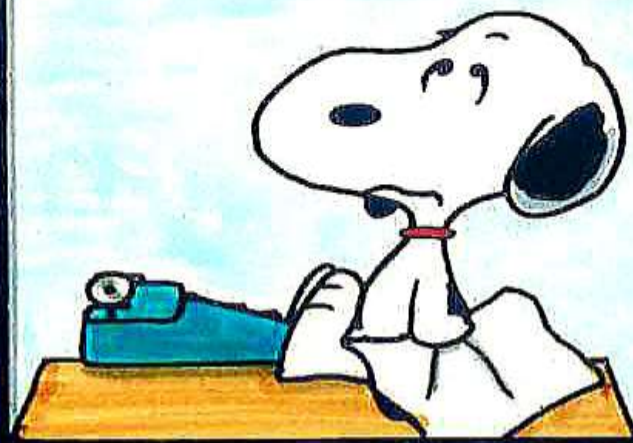
We are returning your
application. It does not
suit our present needs.



P.S. We note that you
sent your application
by first class mail.



Junk mail may be
sent third class.



Schulz

Why Don't Clinical Applications at NIH Fare as Well?

- Potential review factors
 - “density” of clinical applications?
 - Locus of review?
 - Greater cost?
 - Composition of review group?
 - Inappropriate review criteria?

Why Don't Clinical Applications at NIH Fare as Well?

- Potential applicant/application factors
 - Weaker science?
 - Research more difficult?
 - Inadequate clinical research training?
 - Clinical investigators less persistent about reapplying
 - Human subject concerns not adequately addressed

VA “QUERI” Process

- Identify priority conditions and opportunities for improving health of veterans
- Identify effective practices for improving outcomes
- Examine variations in existing practices and their relation to health outcomes

VA “QUERI” Process

- Identify and test variations to improve delivery of best practices
- Evaluate the feasibility, adoption, and impact of improvement programs to disseminate the best practices
- Evaluate the impact of improvement programs on veterans' health

Administrative Approaches to Consider for Peer Review

- Should peer review be conducted by PCORI or by outside contractor?
 - Review history of administrative hassles and costs at NIH
 - DOD contracts out
- Should peer review be separated from program review?
 - VA and foundations tend to blend them
 - NIH does both, depending on locus of review
- Should peer review be by a 2-step process?
 - e.g., pre-application, concept paper, pilot grants
 - DOD, CDC, VA QUERI have 2-step processes

How to capture “Non-Traditional” Perspectives in the Peer Review Process?

- Who are the stakeholders?
 - ethicists, consumers, patient advocates, community partners, health policy experts, others
- How identify and orient stakeholders?
 - Qualifications?
- What are the unique inputs from various stakeholders?
 - Consider stakeholders’ “scorecards”
 - How evaluate their contribution?
 - What are the downsides?
- What are effective formats for involving stakeholders?
 - Include as members of peer review panels (DOD, AHRQ, NIH) ?
 - Separate from scientific review?
 - Evaluate other formats

The role of ethicists in peer review

- Benefitting some groups via research prioritization may harm other groups.
- Benefitting groups may even harm individual members of those groups.
- Adherence to respect for persons tempers the risk of harm to individuals.
- Who is looking after harms to groups?
- Hint: It's not the IRB. They are prohibited from such considerations by the regulations.

The role of ethicists in peer review

- Research prioritization and review raises questions of the distribution of the benefits and burdens of research (Justice)
- Adherence to respect for persons may require that patient perspectives be considered in the discussion.

Research Suggestions for the Peer Review Process

- Evaluate the effectiveness of peer review by determining if PCORI-sponsored research achieves PCORI's goals
- Evaluate the impact of PCORI-sponsored research on each of the following
 - Intermediate outcomes (e.g, publications, grant renewals)
 - Dissemination into clinical practice
 - Long term outcomes (health care)

Research Suggestions for the Peer Review Process

- Identify predictors of success in other arenas (e.g., patents, pharmaceutical companies) and incorporate them into peer review
- Assess approaches for a continuous improvement process for peer review
- Evaluate different models for inclusion of non-scientists in the peer review process
- Evaluate new strategies for implementing patient protection regulations

Recommendations for PCORI Peer Review

- Maintain core values of peer review: scientific competence, fairness, integrity
- Relate criteria for peer review to PCORI's research priorities and agenda
- Support both investigator-initiated and Institute-initiated projects
- Implement a 2-stage peer review process
- Provide feedback and guidance to applicants

Recommendations for PCORI Peer Review

- Maintain core criteria for evaluating all applications, however, modify appropriately for:
 - Investigator-initiated projects
 - Institute-initiated projects
 - Academic/community partnerships
- Involve ethicists, “consumers”, and other stakeholders in the peer review process
- Encourage (?support) prospective studies of the peer review process