PEER REVIEW: A RESEARCH PRIORITY

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The imperative to accelerate translation of discoveries in the basic sciences into the clinical arena is widely acknowledged. Nevertheless, despite doubling of the NIH budget in the past decade, both the Association of American Medical Colleges (AAMC) and the Institute of Medicine (IOM) have expressed concern about the erosion of public trust in clinical research (1-4). Re-engineering the clinical research enterprise was a major theme of the NIH Roadmap for Medical Research, launched in 2003 (5). With the objective of developing an infrastructure to facilitate translation, NIH introduced the Clinical and Translational Science Award (CTSA) in 2005. The Patient-Centered Outcomes Research Institute (PCORI) is another example of a national initiative to provide opportunities for conducting studies to evaluate the impact of scientific discoveries on the treatment and prevention of disease.

Peer review is critical to the process of translation, both to assure scientific rigor and integrity of research proposals. The primary objective of grant peer review is to identify those applications that are most meritorious and worthy of funding. An added challenge for PCORI-based peer review will be to identify those applications that are most likely to fulfill the Institute's overall goals for patient-centered outcomes research.

This report is intended to serve as background for implementing and evaluating a peer review process that is consistent with a patient-centered mission. The report summarizes results of experimental studies of the peer review process and outlines several existing models of peer review. Based on these experiences, as well as interviews with a number of stakeholders and our own experience, the report includes recommendations for implementation of a peer review process charged with the responsibility of identifying the most meritorious patient-centered research proposals.

Additionally, we recommend strategies both to improve the process of peer review and to evaluate the impact of peer review in fulfilling a patient-centered outcomes research mission.

PREVIOUS STUDIES OF THE GRANT REVIEW PROCESS.

Peer review may be considered high quality if the judgments are reliable, valid, and fair (6). The majority of studies of peer review research is based on empirical analyses of these quality traits (7). For example, a potential vulnerability of the peer review process is the lack of concordance among independent assessors. Several decades ago, based on an experiment in which 150 proposal submitted to the National Science Foundation (NSF) were evaluated by two independent sets of reviewers, it was concluded that "whether or not a proposal is funded depends in a large proportion of cases upon which reviewers happen to be selected for it." (8). Based on studies involving NSF, other funding agencies, and manuscript reviews, Cicchetti concluded that referees of grant proposals were more likely to agree about what is unworthy of support than about what does have scientific value (9). Studies of the peer review process in other funding agencies have also reported low reliabilities of grant reviews over a wide range of disciplines (10). One suggestion for reducing "chance" is to give added weight to criteria for which there would be a greater likelihood of agreement among assessors (8). For example, it might be easier for scientists to agree upon the value of recently completed work than on the value of proposed work. Another recommended strategy for improving reliability is to have a small number of experts read and rank all proposals within their discipline (10).

However, increasing reliability does not necessarily increase validity. Differing judgments in peer review may reflect differences in positions, judgment criteria, and areas of competency rather than disagreement about the quality of a proposal (7). Some have argued that high agreement among reviewers may be disadvantageous to the review process: "Too much agreement is in fact a sign that the review process is not working well, that reviewers are not properly selected for diversity, and that some are redundant" (11). Although a strategy of including reviewers with different perspectives may decrease reliability, it would likely enhance predictive validity of the review. Indeed, some have expressed the opinion that low reliability may be helpful for the decision-making process and that reviewers should be selected because of their different perspectives (12). The need to identify suitable criteria for evaluating predictive validity remains a critical issue for research into the review of grant applications.

Overviews of the peer review research literature have named up to 25 different systemic biases (e.g. reviewer and applicant affiliations, "cronyism", age, seniority, gender of applicant, etc) that can potentially endanger the fairness of the peer review process (7, 13, 14). In a blatant example of the potential for introducing bias, some funding bodies allow applicants to nominate their own assessors. Perhaps not surprisingly, applicant-nominated assessors score proposals more favorably than assessors appointed by the funding panel (10). Although one study provided evidence of gender bias (15), this observation was not subsequently confirmed in a number of other studies (16, 17). Overall, published results have not provided consistent evidence across time or funding agencies for an influence of individual biases on

reviewers' judgments (14). One recent study suggests that gender disparity in grant funding is largely explained by gender disparities in academic rank (18). Nevertheless, it would be prudent to design experimental interventions to monitor a potential impact of putative biases on review outcomes. For example, a statistical model has been developed to adjust reviewers' ratings for uncertainties and biases (19). Application of this model to recent R01 rating data at NIH suggested that statistical adjustments to panel rating data would lead to 25% change in the pool of funded proposals.

To evaluate the impact of discussion at the study section meeting on peer review outcome, in R01 applications to NIH, Martin et al studied the relationship between preliminary priority scores of the assigned reviewers and final priority scores given by the review group (20). They concluded that discussion at the meeting had an "important practical impact" on over 13% of the applications.

A recent Cochrane Collaboration study highlights the need and suggests directions for future peer review-related research (21). The Cochrane Group initially undertook a study to evaluate the effect of different peer review processes on the quality of funded research. Based on review of electronic databases and a citation search, only ten retrospective or prospective studies were identified that included two or more comparison groups. The results were as follows:

> Two studies assessed the effect of different ways of screening submissions, one study compared open versus blinded peer review and three studies assessed the effect of different decision making procedures. Four studies considered agreement of the results of peer review processes as the outcome measure. Screening procedures appear to have little effect on the result of the peer review process. Open peer reviewers behave differently from blinded ones. Studies on decision-making procedures gave conflicting results. Agreement among reviewers and between different ways of assigning proposal or eliciting opinions was high.

No studies were identified that assessed the impact of peer review on the quality of funded research. However, there has been little attempt to define "quality", and this represents a challenge for all funding agencies, including PCORI. Without an agreed upon definition of quality, it would seem almost futile to develop peer review strategies that are most likely to detect high quality research.

EXPERIENCE OF GRANT APPLICATIONS FOR CLINICAL RESEARCH IN PEER REVIEW

According to a 1994 IOM report, between 1977 and 1991, priority scores for R01 grant applications to NIH were less favorable for clinical research than for laboratory research (22). In response to increasing evidence cited by clinical investigators that NIH "shortchanges" clinicians and clinical research (23), in 1994, the Division of Research Grants (the predecessor of the Center for Scientific Review [CSR]) at NIH formed a Clinical Research Study Group, chaired by Dr. Gordon Williams. Based on review of more than 6,000 grant applications over two review cycles, the Study Group concluded that patient oriented research applications fared less well than laboratory oriented applications, both in terms of priority scores and funding rates (24). Patient oriented applications that were reviewed in study sections that primarily reviewed laboratory oriented applications were particularly disadvantaged. Subsequently, in 1998, Michael Simmons, MD, serving as a consultant, recommended that CSR make a greater effort to cluster clinical research proposals into "high density" study sections (25), and study sections for cardiovascular sciences and clinical oncology were established.

Using a more inclusive definition of “clinical research”, in several review cycles independently examined between 1984 and 2005, priority scores and funding rates have been less favorable for clinical research project grants than for basic research applications (26-30). This difference was small but consistent and was observed for applications submitted by both MDs and non-MDs. In contrast to Williams’ earlier report, this difference was not found to be related to the “density” of clinical applications reviewed by a study section. The difference was also not related to the reviewers’ experience conducting clinical research or to the greater cost of clinical protocols. One summary report from NIH suggests that in contrast to reviews conducted by CSR, there is no difference in success rates between clinical and non-clinical applications reviewed in the other institutes and centers of NIH (31).

Amended R01 applications and competing renewals fare better in the review process than initial submissions. However, clinical investigators are less likely to submit amended applications and competing renewals than investigators conducting non-clinical research. Based on data from 12 review council rounds, Martin et al reported that the difference in priority scores between clinical and non-clinical R01 applications was reduced with first amended applications and disappeared with second amended applications. This was true for both new applications and competing renewals. Martin et al concluded that a major contributor to the difference in review outcomes between clinical and non- clinical applications was a lower rate of submission of competing continuation applications by clinical applicants (28). In a longitudinal analysis of NIH applicants between 1964 and 2004, Dickler et al observed that physician-investigators consistently experienced higher rates of attrition and failure, even after receiving a first

R01 grant (30). In the Martin analysis, failure of clinical applicants to adequately address human subject protection requirements was another significant factor contributing to the difference in review outcomes between clinical and non-clinical applications. These observations suggest that failure to submit renewal or amended clinical applications and deficiencies in the applications also contribute to their less favorable outcomes.

EXAMPLES OF EXISTING MODELS OF PEER REVIEW

NIH. Since its inception in the mid 1940s, NIH has maintained two underlying principles in its peer review process: a) review by experts; and b) separation of review from program management. In an informative book, Richard Mandel describes the evolution of peer review at NIH from the establishment of the first study section (Syphilis) in1946 to a greatly expanded administrative structure in 1996 (32). The book details the NIH's grappling with a number of procedural issues related to peer review, including the following; an ever expanding workload, review procedures, composition of review groups, impact of fiscal constraints and opportunities, format of the application, development of criteria for evaluating and scoring applications, development of procedures for normalizing scores across review groups, increasing number of regulations regarding the protection of human subjects, computerization of record keeping, and managing the transition to electronic submissions of grant applications. Evaluation and modification of peer review at NIH continues to be an ongoing process. Recent changes include the following: a) decreasing the length of the grant application; b) decreasing the number of allowable amendments for R01 applications from two to one to allow for increased funding of new applications; c) pilot studies of alternative

strategies for review meetings (e.g., “virtual panels”, web-based reviews); d) more flexible schedules for reviewers (33). This history highlights the importance of ongoing evaluation of the peer review process by both internal and external stakeholders, and the willingness and ability to adapt to an ever-changing scientific, political, and fiscal environment.

In the mid 1940s, NIH articulated specific criteria for review. Based on a 1959 review of 605 grant applications to NIH that were disapproved for funding, the most frequent shortcomings were related to either the conception of the research problem, the proposed approach, or the competencies of the investigator (34). Subsequently, review criteria have been enhanced and modified to improve reliability, to decompress scores at the upper end of the scale, and to be more sensitive to the unique merits of clinical investigation. With the intent of increasing the cadre of early stage investigators, recent NIH guidelines provide a “handicap” for them in both the peer review process and funding priorities (33). Some have argued that this preferential treatment undermines the objective of funding “the best science by the best scientists” (35). Following peer review, there is a second level of review by the Institute/Center’s Advisory Council or Board. The responsibility of this body is to advise the Institute/Center Director about final funding decisions, based on the outcome of peer review and the Institute’s/Center’s goals and needs.

Agency for Healthcare Research and Quality. AHRQ uses peer review processes virtually identical to that of NIH, including review format, review criteria, and the scoring system. To assist with the recruitment of peer reviewers, both NIH and

AHRQ have access to a database that includes all previous and currently funded investigators.

Veterans Administration. In contrast to NIH review at CSR, which emphasizes separation of peer review from program review, the Veterans Administration (VA) tends to blend these two review functions. Similarly, foundations also tend to blend the two types of review (e.g., Robert Wood Johnson Foundation, Gates Foundation). The VA uses criteria similar to those of NIH for MERIT grant reviews, with the added criterion of "relevance to the healthcare of veterans."

The VA/HSR&D's Quality Enhancement Research Initiative (QUERI) was launched in 1998 as a system-wide transformation aimed at improving the quality of healthcare for veterans. QUERI contributes to this effort by implementing research findings and evidence-based recommendations into routine clinical practice. Of note, funding for QUERI (~$18 million/year) is not provided from the VA's research appropriation, but rather from dollars appropriated for medical care.

The "QUERI Process" utilizes the following six steps to diagnose gaps in performance and identify and implement interventions to address them (36):

a) Identify priority conditions and opportunities for improving the health of veterans
b) Identify effective practices for improving outcomes for priority conditions
c) Examine variations in existing practices, the sources of variation, and their relation to health outcomes

d) Identify and test variations to improve the delivery of best practices
e) Evaluate the feasibility, adoption, and impact of coordinated improvement programs to spread the best practices
f) Evaluate the effects of improvement programs on veterans' health outcomes, including quality of life.

These steps may be relevant to the PCORI mission and to the development of criteria to evaluate research applications submitted to PCORI. PCORI may also consider adapting some of QUERI's strategies for the conduct of peer review Full QUERI applications (three years) are generally preceded either by a pilot grant (one year) and/or an initial concept paper, submitted through one of the 10 disease-specific "virtual" QUERI centers. Pilot grants and concept papers are reviewed by relatively small ad hoc review groups for scientific soundness and potential to have an impact. Decisions to invite submission of a full proposal are made centrally. Initially, full proposals were also reviewed by small ad hoc review groups. However, reviews were not consistent, and the VA has recently created a study section dedicated to the review of QUERI grant applications. The process of review is similar to that of MERIT review. Membership on the study section includes health services researchers and individuals with relevant operational expertise. Consumers and patient advocates are not represented.

Centers for Disease Control and Prevention. Currently, the CDC uses two approaches in conducting independent review of research applications—either "objective" review or external peer review (37). Objective review is a process that includes an independent assessment of the technical or scientific merit of research by

panels composed of federal reviewers only--predominantly CDC employees. External peer review is an independent assessment of merit by predominantly non-federal reviewers—scientists with relevant expertise. Following this initial review, there is second level of review by either an outside panel of experts or a panel of disinterested senior federal officials who review the ranked proposals to assure maximal impact and balance of the proposed research.

Department of Defense. All research supported by the DOD is in response to a program announcement or an RFP, based on the needs of the agency. The Congressionally Directed Medical Research Programs (CDMRP) of the DOD utilizes a several tiered review system. In a pre-application (pre-proposal) step, applications are screened by a "joint program committee" composed of "science managers" with representation from each of the armed services, and frequently a representative from NIH and the VA. The purpose of this pre-proposal triage is to determine if the hypothesis and aims are consistent with the agency's programmatic objectives. Additional screening criteria include applicant and key personnel, scientific rationale, approach/methods, estimated budget, and existing research investments. Following this initial review, successful applicants are invited to submit a "full application" for external scientific peer review. This review is contracted out to an external agency. The goal is to provide a fair and transparent review that is helpful to the DOD in its subsequent programmatic review prior to making funding decisions for innovative and high-impact research (38). For health care focused applications, based on an IOM recommendation at the time of the introduction of the DOD's breast cancer research initiative in 1993, in addition to scientists, these external panels often include at least 1-

2 “consumers” and clinicians—all with an equal voice. Membership on the panels is not publically available information. Applications are evaluated according to the following scored criteria, which are of equal importance: study design, impact and feasibility, statistical plan, personnel, environment, transition plan, past performance, budget . Following the external review, the DOD conducts a programmatic review (also contracted out to an external agency) to determine the application’s relevance to the mission of the DOD.

Development model. Several elements of a technology development model may be relevant to the review of proposals of patient-centered outcomes research. By analogy, both a research grant and a patent may be considered a “ticket” to move ahead with a research project or with the development of a drug or device. The long term success of a patent is measured by the commercial development of a product. Factors considered in the evaluation of an application for a patent include the following: a) a clear description of the product to be developed and disseminated; b) an understanding of the market for the product; c) a plan for dissemination; d) a plan to incentivize potential partners to collaborate. It may be appropriate to apply similar criteria to the evaluation of patient-centered research protocols.

INVOLVEMENT OF NON-SCIENTIST STAKEHOLDERS IN ESTABLISHING RESEARCH PRIORITIES AND EVALUATING RESEARCH PROPOSALS

Involvement of the community in all aspects of the research process is a potentially powerful approach for restoring the public trust in research (39, 40). The community can be a key stakeholder in establishing research priorities and also in the

conduct and evaluation of research activities. The challenge is to develop effective frameworks and strategies for meaningful community engagement.

Community Engaged Research (CEnR) is a comprehensive and flexible strategy that includes service, learning, capacity building, and community-based participatory research (CBPR) (41). CBPR is "a commitment to conducting research that shares power with and engages community partners in the research process , and that benefits communities involved, either through direct intervention or by translating research findings into interventions and policy change" (42). CEnR maintains that underlying commitment, but with a broader range of methodologies and flexibility regarding the level of community engagement.

The crucial importance of community consultation is exemplified by investigations carried out under the "Final Rule," commonly referred to as Exception From Informed Consent (EFIC). This consultation seeks to engage members of the community and solicit feedback about specific research projects. For example, understanding community perspectives and priorities for research is essential for gaining community acceptance of EFIC studies in emergency medicine, where it is not possible to obtain informed consent (43-45). A number of strategies have been employed to engage the community, , including either convenience sample, random digit telephone surveys targeted focus groups , larger community meetings/public forums, community advisory boards, or some combination of these methods (46-53).

As one strategy for engaging the community, in the early 1990s, NIH established the Council of Public Representatives (COPR). The charge to this committee is to

advise the Director of NIH on matters of public interest, outreach, and participation in NIH's research-related activities. Membership of the committee includes patients, family members of patients, health care and education professionals, and members of the general public. A report emanating from this committee provides guidance for engaging communities in the evaluation of research proposals (54). The Appendix lists COPR's suggested criteria for reviewers to use as a framework for evaluating proposals that involve community engagement as a key component of the research. AHRQ is also developing guidelines for evaluating community-based participatory research proposals (55).

Through several of its award mechanisms, NIH is encouraging the development of academic-community partnerships by inclusion of, "community engagement" as an important component of the award. For example, a "key function" of the Clinical and Translational Science Award (CTSA) is intended to involve health care providers and other stakeholders in the community in establishing research priorities and implementing research protocols with the goal of improving health outcomes and eliminating health disparities in the community. In essence, the CTSA has created a "laboratory" for experimentation in community engagement. While these efforts are new, early reports are promising and detail the usefulness of a bi-directional relationship between academic institutions and community groups in which both groups share responsibility for everything from the development of research goals to human subjects protection (56,57).

Patient advocacy groups constitute another group of stakeholders for establishing research priorities and evaluating the potential impact of research. They

are generally non-profit organizations that focus on specific diseases or aspects of health care. For example, the National Breast Cancer Coalition (NBCC) is a grassroots organization that was founded in 1991 by a group of breast cancer survivors, including its president, Frances Visco. Through a commitment to evidence-based medicine, the primary goal of NBCC is to eradicate breast cancer. Legislative priorities for NBCC include increasing funding for breast cancer research, providing access to quality health care and clinical trials, expanding the influence of breast cancer advocates in all aspects of the breast cancer decision-making process. Frances Visco has effectively testified before congressional committees and has served on Institute of Medicine panels. NBCC's legislative accomplishments include influencing the establishment of establishment of a multi-billion dollar breast cancer research program within the DOD, increased NCI funding for breast cancer research, and several congressional enactment of laws facilitating access to affordable health care. Examples of other effective patient advocacy groups include the TMJ (tempromandibular joint) Association and the National Organization for Rare Diseases (NORD).

COMPOSITION OF PEER REVIEW GROUPS

Both NIH and AHRQ select reviewers primarily on the basis of their scientific expertise and funding. There is an expectation that NIH grantees owe a debt of service at NIH as reviewers. Both NIH and AHRQ have access to the same database for selection of reviewers. Because it is a private Institute, PCORI would not have access to this database. Veterans Administration peer review panel members are recruited from VA medical centers, universities, industry, public and private research foundations, and other federal and state government agencies. Panel members are expected to have

broad knowledge in their areas of expertise, have a history of peer review funding or the equivalent scientific experience, and be leaders in their field.

Several funders include members of the general public on their peer review panels to evaluate proposals from the patient's or family member's perspective (54). In addition to providing a consumer's perspective, engaging the public in a thoughtful and meaningful manner in the peer review process may help to ensure public trust in research. While controversial to many, patients and their advocates have strongly articulated the view that they can provide a unique perspective to the review of clinical research. Funding agencies often find it difficult to assess participatory research proposals, especially if they use traditional review criteria that are not necessarily applicable to participatory research. For example, an AHRQ report has pointed out that when reviewers in a study section are not familiar with or are skeptical about the merits of CBPR, investigators find it challenging to obtain funding for their CBPR projects (58). Some have argued that patients or their advocates have unique insight into certain aspects of clinical research, including the potential impact and feasibility of the proposed work with regard to recruitment issues and human subject protections. However, others argue that the presence of "non-scientists" erodes peer review, since a non-scientist is not a "peer." (54).

Following a recommendation of the IOM, the U.S. Army since 1995 has been including two "consumers"—that is, patients—on each review panel in its research programs on breast cancer, prostate cancer, ovarian cancer and neurofibromatosis. Limited studies of the inclusion of consumers on these review panels suggest that after experience on a review panel, earlier concerns by both scientists and consumers about

consumers' lack of scientific background were not validated (59-64). Having consumers participating on review panels was generally felt to be beneficial.

Under pressure from advocacy groups to open the grant review process, in 1999, NIH began adding lay members to some study sections, and the results have been mixed (64). The National Institute of Mental Health (NIMH) has piloted the use of public reviewers (e.g. mental health consumers, family members, advocates, educators) as full voting members on review committees since 2004. NIMH has found that these reviewers enhance the review process. A recent NIH Peer Review Self-Study recommended that NIH continue to pilot the wider use of patients and/or their advocates on reviews of clinical research (31).

Based on discussion with funding providers and a literature review, an AHRQ committee has recommended inclusion of academic experts for content and individuals with expertise in community based participatory research methodology on application review panels (58). The committee also recommended inclusion of community representatives, and emphasized the need to orient the review panels to effectively tap into the expertise of the community representatives. Strategies for identifying and selecting community representatives/patient advocates were discussed at a recent AHRQ forum (65).

Ethicists, specifically research ethicists, have been included on several research review committees (66-68), including the Recombinant DNA Advisory Committee and on Data Safety Monitoring Boards of clinical trial networks, e.g., the Resuscitation Outcomes Network. Additionally, just as research applicants are expected to anticipate ethical concerns and human subject protections, the peer review process might likewise

incorporate research ethics into its review. Ethicists could also assist by paying particular attention to the execution of patient-centeredness across the research enterprise.

SUGGESTED RESEARCH DIRECTIONS FOR PEER REVIEW

Based on review of the literature and on discussions with key personnel at several of the nation's most prominent funding agencies, it appears that the evolution of strategies for peer review has been based on pragmatism, efficiency, "expert opinions", and political considerations rather than on experimental evidence. For example, somewhat arbitrary decisions have been made about presumptions of recognizing quality research, about the merits and disadvantages of including non-scientists (e.g., consumers, community representatives, patient advocates, ethicists) on review panels, about the inclusion of internal (agency-sponsored) vs. external peer reviewers on review panels, and about the merits if a two stage scientific evaluation process. Each of these approaches would be fertile topics for future investigation. Indeed, the recent Cochrane report highlights a compelling need for experimentation related to making evidence-based decisions about the peer review process (21). In recognition of this need, the International Congress on Peer Review in Biomedical publications was established, and between 1989 and 2009, the Congress has met on six occasions. The aim of this Congress is "to improve the quality and credibility of biomedical peer review and publication and to help advance the efficiency, effectiveness, and equitability of the dissemination of biomedical information throughout the world." There is an even greater paucity of prospective experimentation with peer review for grant applications than with peer review of manuscripts submitted for publication.

In general, there is a need for prospective experimentation both to improve the process of peer review and to evaluate the impact of peer review in fulfilling PCORI's mission. Suggestions for specific research topics include the following:

1. Evaluate the effectiveness of the peer review process by first articulating the goals of overall and project-specific PCORI-sponsored research, and subsequently determining if these goals are achieved
2. Develop strategies to evaluate the impact of science supported by funded grants on each of the following:
    a. Intermediate outcomes (e.g., publications, grant renewals, etc)
    b. Dissemination into clinical practice
    c. Long term outcomes (health care)
3. Identify predictors of success in other arenas (e.g., patents, pharmaceutical companies) and incorporate them into criteria for peer review
4. Evaluate strategies to "capture" perspectives of non-scientists in the peer review process
    a. Who are the stakeholders (e.g. consumers, patients, community partners, health policy experts, others)?
    b. How identify and orient stakeholders? What are their qualifications?
    c. What are the unique inputs of the various stakeholders?
        - Consider stakeholders "scorecards"
        - How evaluate their contribution?

- What are the downsides?

5. Evaluate different formats for involving stakeholders in the peer review process
    a. Include as members of peer review panels (DOD, AHRQ, NIH)?
    b. Separate from scientific review?
    c. Others?
6. Develop a continuous improvement process for evaluating all aspects of the peer review process on an ongoing basis. This would involve defining the process, collecting and interpreting the data, implementing a change, collecting data to determine if the process is improved. The recent Cochrane report highlighted the paucity of prospective studies of peer review in which the design included comparisons of two or more groups.
7. Conduct prospective studies to evaluate different approaches to peer review
8. Evaluate new strategies for implementing regulations for patient protection

RECOMMENDATIONS FOR PCORI PEER REVIEW

Awaiting the availability of results of future experimentation of the peer review process, the following recommendations are based on the literature, experiences of other funding agencies, and PCORI's priorities and research agenda for comparative clinical effectiveness research:

1. Maintain core values of peer review: scientific competence, fairness, integrity.
2. Clarify PCORI's research goals and agenda
3. Relate criteria for peer review to PCORI's research priorities and values
4. Balance the interests of PCORI with the interests of the investigator
    a. Support both broad-based and targeted projects
5. Implement a 2-stage peer review process—stage 1 to evaluate feasibility and relevance of a "concept paper" to the mission of PCORI; submission of acceptable application, by invitation, for full committee review in stage 2
6. Separate responsibility for ultimate funding decisions from scientific peer review
7. Provide feedback and guidance to applicants
8. Maintain core criteria for evaluating all applications, based on criteria specified by the Patient Protection and Affordable Care Act
9. Assign specific weights for each criterion for the following types of projects:
    a. Investigator initiated project
    b. Targeted. Institute initiated project
    c. Clinical trial
    d. Academic/community partnership
10. Include scientists with relevant expertise on peer review groups (e.g., basic scientists and individuals with expertise in clinical trials, population-based studies, statistics)

11. Include other stakeholders in the peer review process(e.g., patients, healthcare providers, , community representatives, health policy experts, ethicist, others)
    a. Evaluate alternative strategies for involving non-scientists
12. Monitor "consistency" of reviews across review groups
13. Develop strategies for identifying, recruiting, and retaining peer reviewers
14. Encourage (?support) prospective studies of the peer review process

Addendum

Based on discussions at the March 6-7, 2012 PCORI Workshop on Methods for Setting Research Priorities (Baltimore, MD), one option for conducting peer review of applications submitted to PCORI may be to contract with the Center for Scientific Review (CSR) at NIH. CSR reviews approximately 70% of all grant applications submitted to NIH, and would be receptive to developing a contractual relationship with PCORI (comments by Dr. Richard Nakamura, Interim Director, CSR). Dr. Nakamura indicated that although PCORI reviews conducted by CSR would have to adhere to NIH's general policies, CSR would be receptive to modifying review criteria and the composition of the review group to accommodate PCORI's research goals. CSR would also be sensitive to the concern that research naïve grant applicants to PCORI might find the NIH grant application process overwhelming. The possibility of a "hybrid" PCORI/CSR review process was also mentioned. These options merit consideration by PCORI.

Appendix—Criteria for research involving communities (54)

TABLE 2—Criteria for Applications for Research Involving Communities

Criteria	Evidence
Peer reviewers understand and have experience conducting research that involves community engagement, as defined by COPR	All reviewers understand the requirements of community engagement in research (CER) to be able to assess community engagement proposals.
Peer reviewers understand the value added by public review panel members	Public reviewers provide the patient or public perspective in assessing a proposal's scientific excellence.[74]
The application provides evidence of an equitable partnership between the investigators and the community partner	The community partner is identified and demonstrates acceptance of its role as a "partner in research." The community of interest is clearly defined.[62]
	Community agencies consistently work with students and faculty through projects that are part of an academic course, community-based research, community service, or other activities.[75]
	Investigators demonstrate involvement in the community; they know which topics are of interest to the community and which community representatives can be brought together to discuss these topics.[41]
	The community partner and investigators share power and responsibilities equally.
In the application, the investigators have defined the relevant community or communities	The community is defined by using explicit criteria, such as common interest, characteristics, or health condition.[76]
In the application, the academic coinvestigators have identified the appropriate community or communities for the project, and the community coinvestigator has identified the appropriate research partner for the project	The academic coinvestigators have identified the community coinvestigators who will participate in the research as partners.[76]
	The community coinvestigators have identified the academic coinvestigators who will participate in the research as partners.
Community engagement is an integral part of the research described in the application	The investigators provide a sound rationale for and record (if applicable) in community engagement. A clear link exists between community-defined priorities and the proposed research focus and approach.[71]
	The proposal addresses not only research methods, but also methods for building and sustaining community partnerships and community participation.[71]
	The proposal includes a management plan for maintaining transparent communications between the community and the academic partners. The investigators describe existing or proposed involvement with one or more community-based organizations.[76]
	The investigators involve the community as an equal partner in the research process, including priority setting, participation, and follow-up.[36]
	Community partner participation may enhance, but does not focus solely on, recruitment and retention of research participants.
The community played an appropriate and meaningful role in developing the application	The letters of support were clearly written by the community, not the investigator.[71]
	The proposal offers evidence that the research planning, organization, structure, and design reflect a true collaboration between the partners.[77]
The application calls for an appropriate division of funding among partners	The amount of funding going to the academic partner and the community is clear, fair, and appropriate.[77]
The research project described in the application is based on sound science	Community engagement projects meet the same rigorous scientific standards as other projects.
	The project addresses an important scientific health problem.[77]
	Achieving the project aims will advance scientific knowledge, community health, or clinical practice.[77]
The project described in the application includes training opportunities	The application includes plans to train investigators, students, and scholars in CER methodology.[36]
	The application includes a plan to train community partners in research methodology. The application includes a plan to train the research team in translating research findings into policy and practice.
The project described in the application will be conducted in an appropriate environment	The environment in which the research will be done enhances the likelihood that the research will succeed.[77]
	The research benefits from unique features of the environment or study population.[77]
	The community benefits from the presence and implementation of the research.
The project described in the application will have a measurable impact	The project will improve public understanding of research.[77]
	The project will produce strategies for promoting collaboration between academic institutions and the community to improve the public's health.[77]
	The research will foster long-term, bidirectional relationships between the academic institution and the community in ways that will benefit both.[36]
	The research will support positive social change in the community's health.

Note. COPR = National Institutes of Health Director's Council of Public Representatives.

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