PCORI Board of Governors Meeting Minutes
November 14, 2011
New Orleans, LA

Public Session A: 1:00 pm – 4:00 pm

Contents

I. Roll Call

a) In Attendance

PCORI Board

Dr. Eugene Washington (Chair), Steve Lipstein (Vice Chair), Dr. Debra Barksdale, Kerry Barnett, Lawrence Becker, Dr. Carolyn Clancy, Dr. Allen Douma, Dr. Arnold Epstein, Dr. Christine Goertz, Leah Hole-Curry, Gail Hunt, Dr. Robert Jesse, Dr. Harlan Krumholz, Dr. Richard Kuntz, Dr. Freda Lewis-Hall, Dr. Ellen Sigal, Dr. Harlan Weisman, Dr. Robert Zwolak

Methodology Committee

Naomi Aronson, Dr. Alfred Berg, David Flum, Dr. Sherine Gabriel, Steven Goodman, Dr. David Meltzer, Brian Mittman, Robin Newhouse, Dr. Sharon-Lise Normand, Mary Tinetti

Staff and Others

Dr. Joe Selby (Executive Director), Dr. Anne Beal (COO), Mark Freeman (Executive Assistant), Heather Meyer (Executive Assistant)

Guests

Dr. Kathy Hudson (NIH), Laura Skoff, (TMC), Gail Shearer (TMC), Shar'on Barclay (TMC), Richard Schmitz (GolinHarris), Erica Fischer (GolinHarris), Josh Weisz (GolinHarris), Jessica Nadler (Deloitte Consulting)

b) Absent

Dr. Francis Collins (represented by Dr. Kathy Hudson) and Dr. Sharon Levine

II. Call to Order

Washington called the meeting to order at 1:04pm.

a) Approval of Minutes

Action

There was a motion and second to approve the September 2011 public session minutes; approved.

b) **Opening Comments from Executive Director**

Selby welcomed Anne Beal to the staff as our Chief Operating Officer. PCORI is currently recruiting for the position of chief scientific officer. The search has been narrowed to final candidates for the director positions of patient engagement, communications, and stakeholder engagement. The plan is to fill the positions by the January 2012 board meeting. In October 2010, PCORI posted for a director of consulting services who will be responding to internal staffing needs related to methodology committee work. The director of scientific review will be responsible for managing the grants processes of solicitation and review. PCORI is also recruiting for PCORI scientists. Dr. Lori Frank is a scientist on board. She will work for the first five months with one of the methodology committee work groups. The director of a finance position has been reposted a controller position. A director of grants management position has also been posted. Heather Meyer is now on board as Selby's executive assistant. Denise Earlington will be on board soon Beal's executive assistant.

Selby continued by reporting some of PCORI's accomplishments over the last two months. Three RFPs have been issued. Eight awards were given, totaling $800,000. The program development committee issued the first funding announcement for the pilot projects. Review criteria were defined, and eight key areas of interest identified. Over 1,000 letters of intent have been received. The anticipation of more than 1,000 completed applications by December 1 is expected. Nearly 500 volunteer technical reviewers and 300 stakeholder reviewers have been identified. For those stakeholders who need it, a training session will be provided. The grants management process is in progress with support to the board's role in final approval.

At PCORI, the work is on a foundation of engagement of patients and other stakeholders with research, infrastructure development, training and capacity building, and dissemination as the core activities. The obligation is to get $160 million funded in 2012. The national priorities and research agenda will be put out for public comment and inform the funding announcements. This month and next, PCORI is interviewing patients and other stakeholders in focus groups.

c) **Program Development Committee Report**

Epstein reported on the development of the national priorities. The five priorities we've identified are:

A. comparative clinical effectiveness
B. improving health care systems
C. communication and dissemination

D. fairness/addressing disparities
E. accelerating patient-centered research

Two criteria are proposed outside of the eight defined in the statute; novel use of technology and efficient use of research resources. PCORI wants to refine the proposal through public comment and stakeholder engagement. The first version of the national priorities is slated to be published in March 2012.

Kuntz reported on the research agenda. The distinctive features of PCORI's research agenda are:

A. promote patients as partners, with a role in the design, governance, review and dissemination of research
B. declare and implement a commitment to open access
C. emphasize reusable, sustainable research structures
D. focus on real patient outcomes
E. emphasize scalable knowledge that's suitable for dissemination an application
F. fund efforts that produce useful tools
G. emphasize ideas that emerge from the community
H. link from the outset with those will likely use the products of research
I. measure success by the impact on patient outcomes
J. emphasize rapid-cycle, inexpensive research
K. develop novel IT strategies

Kuntz continued that PCORI has received more than 1,300 letters of intent which has been a great collaborative effort with the staff, Goertz and Hunt.

Goertz reported that PCORI issued the first announcement and hosted three webinars to answer questions due to the level of interest. Approximately, 1,375 letters of intent were received along with 350 stakeholder reviewer applications and nearly 500 technical reviewer applications. More than 1,400 letters of intent were logged into a database. They were reviewed and sent to NIH, so they can begin their planning of the application review. There are four steps to the review process: the preliminary check, a merit review, deliberation and business. Once it's determined the application meets the technical requirements, it will be assigned to three reviewers. Merit review is slated for end of February 2012. Award notifications will be in May 2012.

Washington stated that the public comment period will take place on Tuesday, November 15. Today's comment period is structured with an invited stakeholder panel.

PCORI Board of Governors Meeting Minutes
November 15, 2011
New Orleans, LA

Public Session B: 8:00 am – 12:00 pm

Contents

I. Roll Call

a) In Attendance

PCORI Board

Dr. Eugene Washington (Chair), Steve Lipstein (Vice Chair), Dr. Debra Barksdale, Kerry Barnett, Lawrence Becker, Dr. Carolyn Clancy, Dr. Allen Douma, Dr. Arnold Epstein, Dr. Christine Goertz, Leah Hole-Curry, Gail Hunt, Dr. Robert Jesse, Dr. Harlan Krumholz, Dr. Richard Kuntz, Dr. Freda Lewis-Hall, Dr. Ellen Sigal, Dr. Harlan Weisman, Dr. Robert Zwolak

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Naomi Aronson, Dr. Alfred Berg, David Flum, Dr. Sherine Gabriel, Steven Goodman, Dr. David Meltzer, Brian Mittman, Robin Newhouse, Dr. Sharon-Lise Normand, Mary Tinetti

Guests

Dr. Kathy Hudson (NIH), Laura Skoff, (TMC), Gail Shearer (TMC), Shar'on Barclay (TMC), Richard Schmitz (GolinHarris), Erica Fischer (GolinHarris), Josh Weisz (GolinHarris), Jessica Nadler (Deloitte Consulting)

b) Absent

Dr. Francis Collins (represented by Dr. Kathy Hudson) and Dr. Sharon Levine

II. Agenda Items

a) Methodology Committee Report

Gabriel reported that the methodology committee is on track to produce the report in 2012. The methodology committee is organized into four working groups.

Patient-Centeredness Working Group

Tinetti reported this group wanted to make sure the voice is incorporated into every aspect of the work including the development and prioritization of research questions, the design of study components and the processes of clinical decision-making. The following institutions have been contracted to conduct stakeholder interviews and a literature review with the purpose of eliciting the patients' perspective in patient-centered outcomes research:

- Oregon Health & Science University – stakeholder interviews
- Mayo Clinic – literature review
- University of Maryland – stakeholder interviews for hard-to-reach populations

Twenty-one proposals were received from sixteen institutions. Communication takes place weekly with these three contractors. The plan is to have reports in March 2012.

Research Prioritization Working Group

Slutsky reported that the objective is to commission and synthesize white papers on topic generation, gap analysis in systematic reviews, value of information analysis, and peer review. PCORI awarded contracts to the following organizations for white papers:

- Hayes Inc. – topic generation
- National Opinion Research Center – value of information analysis to inform PCORI research priorities
- Duke University – value of information analysis to inform PCORI research priorities
- University of Wisconsin – role of peer review

Research Methods Working Group

Newhouse reported that this group's goal is to identify standards for the use of data, design, and statistical analysis to conduct PCOR through development of a translation tool, reviewing current "state of the art" statements on methodology, and reviewing existing data systems. An RFP was issued for review of guidance documents for selected methods of PCOR. The plan is to be completed in March 2012. An RFP will be issued for case studies for the development of a methodology translation tool. There have been thirty-three interviews conducted including government, commercial, and academia to assess how electronic health records and data systems are leveraged for CER/PCOR.

Assimilation Working Group

Berg reported that this group is the report coordinators. The following process is being developed to recommend proposed methodological standards:

- Confirm working definitions
- Sources of proposed standards
- Support for proposed standards
- Committee criteria
- Final standard selection

Gabriel continued that the methodology committee will meet April 3, 2012 in Washington, DC to finalize standards that will be included in the May 2012 report. There have been seven contracts awarded, to date. The purpose of the proposal review process was to evaluate the proposals for three funding opportunities. They were reviewed for technical requirements, content, programmatic aspects, and then a decision were made.

b) Finance Committee Report

Barnett reported in 2012, PCORI will do a quarterly review instead of at each board meeting. Through Oct. 31, there is $45.4 million in assets against liabilities of $1.3 million. PCORI is currently operating under budget by $7.8 million. The total expenses, year to date, are $5.4 million.

The bylaws are scheduled to sunset at the end of this calendar year. PCORI will need to consult with the GAO on two provisions related to term limits which they've taken under advisement. So, these have been removed for now. The proposal is to adopt these new bylaws today. An amendment can be done at a future date upon receipt of response from the GAO. There have not been any substantive changes to the bylaws since the last review. The changes include language related to committee structure, creation of a nominating committee, amendments, duties of vice chair, board actions by unanimous written consent, and annual review of the executive director.

Action

There was a motion and second to approve the bylaws; approved.

There are some proposed changes to the compensation policies around meeting fees and monthly stipends for board members. Some reporting was done to help set these rates. The results of this were inconclusive. This will be revisited in 2012 when the organization is on a more even keel in terms of time commitment. The revised policy has essentially two changes. One, the policy now applies to the methodology committee in addition to the board, and two, it adds a provision for special assignments. The intent is for this to be used very sparingly. The language has been simplified.

Clancy noted that for the record that the named federal representatives do not accept the stipends or travel support.

Action

There was a motion and second to approve the compensation policy with an amendment that the board will be notified of any special exceptions; approved.

Barnett continued that an audit firm has been selected. Some consultants gave PCORI some advice and help with the RFP. The RFP went to eleven firms; eight participated in a bidder's conference; five responded with a proposal. The audit firm selected is McGladrey, a firm with extensive not-for-profit experience and a team in Washington, DC.

As PCORI moves forward with the strategic planning, budget adjustments will likely be necessary in early 2012. We will be vote on a budget at the January meeting. The dollars ramp up significantly in 2012 with a spend of about $160 million.

Selby reported on the planning and budget for 2012. The board is committed to the 2012 allocation on pilot projects, contracted research, grants, growing the staff, and increasing level of stakeholder engagement activities. Several meetings are planned for 2012; the establishment of several advisory panel, landscape reviews, and initial planning for a 2013 conference are also planned.

Becker reported on the conflicts of interest policy. A recommendation is in place for a standing committee for conflicts of interest. It would include four outside members – an ethicist, an attorney, a patient advocate, and a consumer representative. The standing committee would make recommendations to the board. The board would have final authority, with an appeals process. The general guidelines would be the ineligibility of research funding for board members and close relatives; no direct or indirect benefit to a board member; board members must recuse themselves from decisions involving their employer; and methodology committee members are ineligible if involved in developing the grant application. For future RFPs, a recommendation is made for staff review applications and includes information in a report of involvement of board members for the sake of transparency. The standing committee would address questions, if needed. The starting assumption is that board and methodology committee members, spouse and close relatives are ineligible to receive PCORI funding. Staff will prepare a report to the standing committee for each grant, who will in turn make a recommendation to the board. Any exceptions will be considered in an open board meeting.

III. Public Comments

Washington opened the floor to public comments.

- Michael Ellis, MD – Tulane & LSU schools of medicine
- Jose Calderon, MD – Consortium of Academic Centers for Integrative Medicine
- Kimberly Richards, PhD – Common Ground Health Clinic
- Juan DeShan, MD – Tulane School of Medicine & Charity Hospital

Communication, Outreach and Engagement Committee Report

Weisman reported on behalf of Sharon Levine. Considerable progress has been made in digital communications. The website is improving each week. The email list is growing with more than 1,000 names. ARHQ has been very helpful to broadcast announcements. Traffic to the website has grown exponentially. On October 25, a Twitter account was launched. There has been good success with the initial funding announcements through the email outreach and media relations. Flum of the methodology committee is leading the work on revising the working definition of PCOR. Through the bidding process, NORC has been asked to synthesize all the comments gathered in a 45-day period as phase 1.

The second phase includes focus groups. Focus groups begin next week in Chicago, then Richmond, and Phoenix. The guide to the focus groups is available to board members. As of today, there have been over 50 official PCORI presentations as part of the speakers' bureau activities.

Selby stated that PCORI is doing a public meeting with AMA in December.

IV. Adjournment

Washington adjourned the meeting at 11:47 a.m.