# PCORI Board of Governors Meeting Minutes
# JULY 18, 2011
# Washington, D.C.

## Public Session B: 1:00 pm – 4:00 pm

### Contents

# I. Call to Order

Washington called the meeting to order at 1:03 p.m. He welcomed those in attendance and reminded all that the meeting was being webcast live.

# II. Roll Call

## a) In Attendance

### *PCORI Board*

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

### *Methodology Committee*

Sherine Gabriel (Chair), Sharon-Lise Normand (Vice Chair), Naomi Aronson, Ethan Basch, Alfred Berg, David Flum, Steve Goodman, Mark Helfand, Michael Lauer, David Meltzer, Robin Newhouse, Sebastian Schneeweiss, Jean Slutsky, Mary Tinetti, Clyde Yancy

### *Staff*

Joe Selby (Executive Director)

### *Guests*

Kathy Hudson (NIH), Art Herold (WC&B), Pat Nichols (TMC), Laura Skoff (TMC), Shar'on Barclay (TMC), Bill Hubbard (TMC), Gail Shearer (TMC), Wanita Thompson (Trissential), Nancy Miller (Trissential), Joe Clayton (GolinHarris), Richard Schmitz (GolinHarris), Erica Fischer (GolinHarris), Mark Freeman (Temporary Executive Assistant)

## b) Absent

Francis Collins (represented by Kathy Hudson)

## III. Agenda Items

### *Action*

There was a motion and second to approve the May 2011 public session minutes with one minor change to attendance (acknowledging the presence of Debra Barksdale by phone); approved.

### a) Opening Comments from Executive Director

Selby expressed gratitude to the board for putting their trust in him. He thanked the interim staff for all their assistance in the transition and congratulated them on the quality of their work prior to his arrival. Selby reported that PCORI has a temporary location at 1701 Pennsylvania Avenue NW in the District. The anticipation is to be in this location through the end of the year. PCORI has engaged a broker to help locate permanent space in the Washington DC metro area. The space needs are for approximately 30-35 staff and patient-centered in design and functionality. An HR consulting firm has been hired to help PCORI develop policies and benefits. A search is underway for both a COO and fiscal officer through the search firm KornFerry.

Selby concluded by commenting that for the long-term mission, there are three areas of focus: stakeholder engagement, research, and dissemination.

### b) Communication, Outreach and Engagement Committee Report

Levine reported that the committee name change from Public Affairs & Communications Committee to better reflect the work of the committee. The charter is to advise and assist the board and provide recommendations on branding, stakeholder engagement, and dissemination of information. She noted that at the May meeting, the committee was asked to recommend a process for receiving broad public input on the methodology committee's working definition of PCOR. A two-phase process was recommended. Although it goes beyond the statutory requirements, it is deserving of this level of attention.

### *Phase 1*

This phase will consist of a 45-day web-based survey with email and mail options. The survey will be promoted to all stakeholders and the general public but there is anticipation that the response will be highest from stakeholder organizations and healthcare professionals.

### *Phase 2*

This phase will consist of conducting patient-focused testing of the definition following an analysis of what is received in Phase 1. Focus groups in English and other languages will yield good qualitative data.

At each of the last two board meetings, more than 100 people participated in stakeholder meetings. The summaries are provided on the website.

Levine concluded that there is a plan is to do a comprehensive revamp of the PCORI website once the logo is approved.

### *Action*

There was a motion and second to approve the two-phase survey process; approved.

## c) Mission Statement and Logo

### *Action*

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

Lipstein reported that PCORI began discussing the mission statement at the first meeting in November 2010. A working group was formed and began discussions in depth in March 2011. The group looked at three factors:

- **What:** PCORI produces and promotes high-integrity, evidence-based information.
- **Why:** To help people make informed health care decisions, and to improve health care delivery and people's experiences, decisions, and outcomes.
- **How:** By partnering with patients, caregivers, and the broader health care community to guide all aspects of PCORI's work.

## d) The Consensus Mission Statement

"The PCORI helps people make informed health care decisions - and improves health care delivery and outcomes - by producing and promoting high-integrity, evidence-based information - that comes from research guided by patients, caregivers, and the broader health care community."

Lipstein asked that the board approve the mission statement as is with the understanding that the statement may be revisited to include the words "trusted" and/or "helpful".

***Action***

There was a motion and second to approve the PCORI mission statement; approved.

## e) Public Comments

- John Lewis - Association of Clinical Research Organizations
- Dr. Timothy Fabian - National Trauma Institute - University of Tennessee-Memphis School of Medicine
- Kathleen Teixeira - The Partnership to Improve Patient Care - American Gastroenterological Association
- Perry Cohen - Parkinson Pipeline Project
- David Shern - Mental Health America
- Ann Gianola - Adult Congenital Heart Association
- Dr. Peter Lavin - Medical Society of the District of Columbia
- Louise Kaplan - American Nurses Association
- Diane Dorman - National Organization of Rare Disorders
- Dr. J.D. Singh - Prince George's Hospital Center

Washington thanked the public for their comments and encouraged others who were listening or watching the live webcast to submit comments via the PCORI website.

## f) Methodology Committee Report

Gabriel reported that the committee is committed to ensuring that everything the committee does is in alignment with the statute. The overarching goals of the Translation Table and Methodology Report are to provide guidance for PCORI, identify what is not known, reinforce ongoing methodological focus, and to disseminate information. The committee has four working groups, as follows:

- To identify methods for incorporating the patient perspective into all phases of PCOR.
- To focus on incorporating the patient perspective into the study design.
- To determine how the patient perspective gets incorporated into the process of clinical decision-making and care delivery.
- To assimilate all this information to reflect PCORI's vision.

The Methodology Committee plans to do workshops for the 1st Quarter of 2012 and the mandated report is due in May 2012. An outline of the report may be ready for the September board meeting.

# *IV. Adjournment*

The meeting adjourned at 5:28p.m.

# PCORI Board of Governors Meeting Minutes
# July 19, 2011
# Washington, D.C.

## Public Session A: 8:00 am – 12:00 pm

### Contents

# I. Call to Order

Washington called the meeting to order at 8:03a.m. He welcomed the public attendees. He reminded all that the meeting was being webcast live.

# II. Roll Call

## a) In Attendance

### *PCORI Board*

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

### *Methodology Committee*

Sherine Gabriel (Chair), Sharon-Lise Normand (Vice Chair), Naomi Aronson, Ethan Basch, Mark Helfand, Michael Lauer, David Meltzer, Sebastian Schneeweiss, Jean Slutsky

### *Staff*

Joe Selby (Executive Director)

## b) Guests

Kathy Hudson (NIH), Art Herold (WC&B), Pat Nichols (TMC), Laura Skoff (TMC), Shar'on Barclay (TMC), Bill Hubbard (TMC), Gail Shearer (TMC), Wanita Thompson (Trissential), Nancy Miller (Trissential), Joe Clayton (GolinHarris), Richard Schmitz (GolinHarris), Erica Fischer (GolinHarris), Mark Freeman (Temporary Executive Assistant)

# III. Agenda Items

## a) Program Development Committee Report

Kuntz reported that PCORI's core priorities are the national priorities and the research agenda. Supporting programs include the landscape reviews, Tier One grants, conference grants, and "incentive" grants. The landscape reviews will provide analysis of the capacity of conducting research, existing studies, and dissemination science.  Some landscape reviews are underway.  The Peer review model for Tier One grants will engage stakeholders in a novel manner. Conference grants are one-year small group grants.  The innocentive grants are competitive and aimed at solving specific problems.

Goertz reported on the Tier One Pilot Projects.  She noted that PCORI is mainly interested in projects that are focused on developing, testing, and/or evaluating methods or approaches that do the following:

- Inform the national priorities
- Bring together stakeholders
- Translate research into practice
- Identify gaps relative to disadvantaged populations
- Identify predictors of outcomes. (Refer to slide 13.)

A thirty-day opportunity will be open August 1, 2011 for public input on these broad areas of interest prior to completion and release of the funding announcement.  A letter of intent will be due as the first step in the application process.  Grant applications will go through a scientific and stakeholder review as well as a programmatic review by the board.   The recommendation is to contract with NIH for the first PCORI review due to the sense of urgency in moving forward.  NIH has a standard, trusted approach. PCORI will select the reviewers, review criteria and will do the final selection.  The review process has six stages:

A. A letter of intent will be required. This will help to estimate the number of applications to expect.
B. NIH will review applications to ensure technical requirements are met. Grant applications will be reviewed by NIH to assess the scientific content and identify the level of expertise needed by the scientific and stakeholder reviewers.
C. Grant applications will be reviewed by PCORI staff to assess programmatic areas of interest.
D. Peer review of applications by scientists and stakeholders. Written critiques are prepared by reviewers, and then discussed in a meeting. NIH staff will prepare a summary of the reviews and the applications will be scored.
E. PCORI board members will convene a meeting to review the summaries and scores.  Funding decisions will be made.
F. PCORI staff will review selected applications for fiscal compliance with PCORI policies and procedures.

The timeline is to make the funding announcement in September 2011. The letter of intent will be due November 1, 2011. Applications will be due in December 2011. The peer and PCORI review will happen in the 1st Quarter of 2012. Lastly, the awards will be issued in April 2012.

## b) Finance and Administration Committee Report

Barnett reported that the committee's major undertaking since the last board meeting has been related to office space and staffing.

### *Action*

There was a motion and second to allow executive staff members to sign PCORI checks and authorize expenditures; approved.

Barnett continued that the board members and methodology committee members are entitled to compensation and it is the same based on average time commitment. The committee is analyzing the process and will make recommendations at a later date. The preliminary methodology committee budget is just shy of $3 million for the remainder of this calendar year.

### *Action*

There was a motion and second to approve the Methodology Committee budget as part of the previously approved organizational budget; approved.

The financials reflected total assets of $48 mil; liabilities $700,000; fund balance of $47.2 mil. Total expenses year-to-date $2.3 mil. Expenses are under budget $1.6 million overall and under budget in nearly every line item with exception of meeting costs. Activities are ramping up more slowly than anticipated and/or budgeted. The next report will include the new methodology committee budget built in. PCORI will maintain a cash balance that is equal to our accounts payable and our contracted obligations. Those cash needs are being assessed.

Barnett noted that the next item to discuss refers to PCORI's bylaws. They expire at the end of 2011. A proposal has been circulated for feedback. The committee will come back to the board with a revised bylaw document to vote on at a future board meeting.

The committee is proposing the following:

- The creation of a nominating committee; specifically stating three standing committees. (Note: take another look at the notes. This would be the fourth standing committee).

- Authority of Chair to create temporary committees and working groups.
- Some changes to the section about the methodology committee
- Board action by unanimous written consent when meetings are not possible.
- Term limits for chair and vice chair.
- Performance review of executive director and officers of the organization.

The last item of discussion related to a conflict of interest policy. The board has already adopted a policy but there are other issues we need to deal with such as a policy that covers third parties.

## *IV. Public Comments*

- Dr. Fred Edwards - The Society of Thoracic Surgeons - University of Florida
- Lisa Simpson - Academy Health
- Amy Miller - Personalized Medicine Coalition
- Vera Jackson - Epilepsy Foundation Greater Washington
- Janet Kahn - Consortium of Academic Health Centers for Integrative Medicine
- Andrew Spurling - National Alliance on Mental Illness
- Russ Glasgow - National Cancer Institute
- Perry Cohen - Parkinson Pipeline Project

Washington encouraged others who were listening or watching the live webcast to submit comments via our website.

## *V. Adjournment*

The meeting adjourned at 11:40 a.m.