MINUTES OF THE PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE BOARD OF GOVERNORS MEETING THE FAIRMONT COPLEY PLAZA HOTEL BOSTON, MASSACHUSETTS NOVEMBER 19, 2012

Board Members Present: Eugene Washington, MD, MSc, *Chair;* Steven Lipstein, MHA, *Vice Chair;* Debra Barksdale, PhD, RN; Kerry Barnett, JD; Lawrence Becker; Carolyn M. Clancy, MD; Francis S. Collins, MD, PhD; Leah Hole-Curry, JD; Allen Douma, MD; Arnold Epstein, MD; Christine Goertz, DC, PhD; Gail Hunt; Robert Jesse, MD, PhD; Harlan Krumholz, MD; Richard E. Kuntz, MD, MSc; Sharon Levine, MD; Freda Lewis-Hall, MD; Grayson Norquist, MD, MSPH; Ellen Sigal, PhD; Harlan Weisman, MD; Robert Zwolak, MD, PhD

Methodology Members Present: Naomi Aronson, PhD; Sherine Gabriel, MD, MSc; Mark Helfand, MD, MS, MPH; Michael Lauer, MD; David Meltzer, MD, PhD; Brian Mittman, PhD; Robin Newhouse, PhD, RN; Sharon-Lise Normand, PhD; Sebastian Schneeweiss, MD, ScD; Jean Slutsky; Mary Tinetti, MD; Clyde Yancy, MD, MSc

Staff: Ayodola Anise, MSH; Anne Beal, MD, MPH; *Deputy Executive Director and COO,* Chad Boult, MD MPH; Kelton Chapman; James Convery, MBA; Martin Duenas, MPA; Denise Earlington; Jordan Elliker; Mark Freeman; Rachael Fleurence, PhD; Desiree Frank; Lori Frank, PhD; Orlando Gonzales, MPA; Pam Goodnow, CPA; Sean Grande; Romana Hasnain-Wynia, PhD; David Hickam, MD, MPH; Susan Hildebrandt, MA; Kara Odom Walker, MD; Michele Orza, ScD; Gail Shearer, MPP; Joe Selby, MD MPH *Executive Director;* Sue Sheridan, MBA, MIM; William Silberg.

Guests:
Sean Magers, Nancy Miller (NIH), Lauren Saxton (Oregon Health & Science University)
Richard Schmitz (Golin Harris), Annette Totten, PhD, MPA (Oregon Health & Science University)

Public Commenters: Dave deBronkart, Cristin Lind, Sally Okun, Danny van Leeuwen, Amy Whitcomb Slemmer

Agenda

MONDAY NOVEMBER 19	AGENDA ITEM OPEN MEETING	Result
7:30 – 8:30 AM	**Breakfast**	
8:35 – 8:39 AM	**Welcome and Approval of May and September 2012 Board Meeting Minutes** - *Eugene Washington*	May 20th and September 24th Minutes Approved Unanimously
8:39 – 8:55 AM	**Executive Director's Report** - *Joe Selby* Executive Director Selby updated the board on recent PCORI engagement activities, and on staff growth. He announced the creation of the Chief Officer for Engagement position and announced that Dr. Anne Beal has been named Deputy Executive Director as well as Chief Operating Officer.	
8:55 -10:14 AM	**Adopting Methodology Committee Revisions** - *Sherine Gabriel, Lori Frank* MC Member Gabriel updated the Board on the activities of the Methodology Committee and presented the revised Methodology Standards and Recommended Actions for Board consideration and approval. Member Collins asked how PCORI is going to assess that standards are working and being adhered to. Gabriel said that PCORI will establish an evaluation plan that can monitor the data as it comes in to make sure the standards are being adhered to. MC Member Mittman added that they will look to the field of implementation science and clinical practice guidelines of other standards in the field for guidance. Executive Director Selby pointed out the importance of peer reviewers in the process and said that the PCORI staff will be working with the Methodology Committee to find the best way to prepare peer reviewers. Chairman Washington said that he expects staff to work with the Board on the evaluation proposal. Several board members suggested that it may be valuable for the Board to consider the revisions for a period of time and then have a follow-up conversation with the MC before voting to approve. Member Norquist moved to approve the revised Standards	17 votes in favor 4 votes opposed 0 abstentions (The vote was 17-4; Leah Hole-Curry, Freda Lewis-Hall, Gail Hunt and Harlan Weisman voted against)

	and Recommended Actions. Member Hole-Curry seconded the motion. After discussion, the motion was approved with 16 members in support, 4 in opposition, and zero abstentions.	
10:14 – 10:35 AM	**Break**	
10:35 – 11:37 AM	**Advisory Panel Charters** - *Anne Beal* Deputy Executive Director and Chief Operating Officer Beal presented to the Board PCORI's proposed Advisory Panels and charters for Board review. After discussion, the Board recommended to proceed with soliciting interest and preparing slates of advisory panel members for the initial three advisory panels: Patient Engagement; Assessment of Prevention, Diagnostic and Treatment Options; and Addressing Disparities. Executive Director Selby emphasized that these panels are only advisory, and that the Board will ultimately have the final say on funding. They will also work on prioritizing research projects, among other topics. Chairman Washington asked that an advisory panel roadmap be devised to clarify their roles, level of engagement, and the information process. Chairman Washington also recommended that each advisory panel have a Board member enrolled as an ex officio member, and that if possible the advisory panels meet at the same time and place in order to allow for a plenary session of some sort. The Board also indicated that Staff could proceed with exploring the possibility of additional advisory panels. It was also recommended that the panel charters come up for review after one year instead of two years and that there be a rigorous evaluation process in place.	
11:38 – 1:45 PM	**2013 Budget** - *Anne Beal, Pamela Goodnow, Kerry Barnett* Member Barnett, Deputy Executive Director and Chief Operating Officer Beal and Staff Member Goodnow presented the proposed PCORI Budget for 2013. In response to Board questions about a discretionary	

	research fund in the amount of $6 million, Executive Director Selby pointed out that the decision-making structure would still require that he return to the Board for any expenditure over $500,000. The Board asked that Staff develop an estimate of the proportion of the total budget going directly to research, and make other revisions to the MC budget and to the Engagement budget which will be presented at an upcoming Board meeting.	
12:12 – 1:12 PM	**Lunch**	
1:45 – 2:08 PM	**Pilot Project Oversight** - *Lori Frank* Staff Member Frank gave the Board an overview PCORI's Pilot Project program and updated the Board on the Pilot Project Management.	
2:08 – 3:01 PM	**PFA Cycle One Review Update** - *Martin Duenas, Joe Selby, Anne Beal* Staff Member Duenas presented and the Board discussed the current status of the Cycle One review process. Executive Director Selby said a selection committee will be comprised and meet twice before the December (webcast) Board meeting. Data will gathered and examined on a wide range of variables related to the applications. These variables will be considered, both on the projects funded and those that did not make the cut. The selection committee will focus primarily on the priority score and two variables: the population studied and the condition studied in determining whether the ranked proposals identify a balanced set of studies. A slate of proposals will be recommended and presented to the Board at the December meeting for approval.	
3:01 – 3:20 PM	**Break**	
3:20 – 4:12 PM	**Targeted PFAs** - *Joe Selby, Kara Odom Walker* Executive Director Selby and Staff Member Kara Odom Walker presented and the Board discussed PCORI's Targeted PFAs and Initial Targeted Funding Announcements. Chairman Washington recused himself from this discussion.	18 votes in favor

	Walker described the prioritization process and presented the three topics that were highest priority: treatment options for uterine fibroids; treatment and management of severe asthma in minority populations; and prevention of falls in the elderly. Member Douma asked if PCORI could make the scores available for the Board and the public. Executive Director Selby said that the data will be prepared and shared with the Board and posted once it is organized. After discussion, Member Becker moved to approve the first round of three targeted PFAs. Member Zwolak seconded, and the motion was approved with 17 votes in favor, 2 opposed, and one recusal. In the coming months, Staff will disseminate to the Board a list of other possible PFAs, from which the Board will select an additional two. These five will then be the subject of 5 expert/stakeholder workshops that consider an area and aim to identify the key research question(s) in that area.	2 votes opposed 1 recusal (The votes were 18-2; Alan Douma and Harlan Krumholz voted against and Eugene Washington recused himself)
4:19 – 4:41 PM	**Public Comment Period** Comments were received from Dave deBronkart, Danny van Leeuwen, Amy Whitcomb Slemmer, Cristin Lind, and Sally Okun.	
4:42 – 4:54 PM	**Nominating Committee** - *Steve Lipstein* Member Lipstein presented the Nominating Committee's proposals for the composition and chairs of Board committees beginning January 1, 2013, including the Finance, Accounting and Audit (FAAC), Communications, Outreach and Engagement (COEC), the Program Development (PDC), the Scientific Publications Committee, the Standing Committee on Conflict of Interest (SCCOI), the Executive Compensation Committee (ECC), and the Nominating Committee. The nominating committee also proposed the appointment of Dr. Robin Newhouse as vice-chair of the Methodology Committee, beginning January 1, 2013. After discussion, Member Lipstein moved approval of all nominations, Member Clancy seconded, and the	21 votes in favor 0 votes opposed 0 abstentions

	recommendations were approved by the Board unanimously.	
4:55 - 5:08 PM	**Wrap-up and Adjourn**	
6:00 – 8:00 PM	**Reception / Dinner**	