



# Patient-Centered Outcomes Research Institute Board of Governors Meeting Minutes

Renaissance Dupont Circle Hotel  
1143 New Hampshire Avenue, NW  
Washington, DC 20037  
September 15, 2014

## **Board Members Present:**

Grayson Norquist, MD, MSPH, *Chair*; Debra Barksdale, PhD, RN; Kerry Barnett, JD; Lawrence Becker; Allen Douma, MD; Arnie Epstein, MD; Alicia Fernandez, MD; Christine Goertz, DC, PhD; Leah Hole-Marshall, JD; Gail Hunt; Richard Kronick, PhD; Harlan Krumholz, MD; Richard Kuntz, MD, MSc; Michael Lauer, MD (designee for Francis Collins, MD, PhD); Sharon Levine, MD; Freda Lewis-Hall, MD; Steve Lipstein, MHA; Ellen Sigal, PhD; Harlan Weisman, MD; Robert Zwolak, MD, PhD

## **Board Members Absent:**

Robert Jesse, MD, PhD

## **Methodology Committee Members Present:**

Robin Newhouse, PhD, RN, *Chair*

## **Staff:**

Joe Selby, MD, MPH, *Executive Director*; Matt Burrell; Steven Clauser, PhD, MPA; Emma Djabali; Laura Forsythe, PhD, MPH; Desiree Frank; Orlando Gonzales, MPA; Pam Goodnow, CPA; Annie Hammel; Romana Hasnain-Wynia, PhD; Mary Hennessey, Esq., *General Counsel*; David Hickam, MD, MPH; Susan Hildebrandt, MA; Lauren Holuj; MHA; Kim Jackson, CPA, MBA; Jayne Jordan; Kristen Konopka, MPH; Maggi LeDuc; Bryan Luce, PhD, MBA, *Chief Science Officer*; Penny Mohr, MA; Kara Odom Walker, MD, MPH; Michele Orza, ScD; Katie Rader; Sue Sheridan, MBA; Bill Silberg; Jean Slutsky, PA, MSPH, *Chief Engagement and Dissemination Officer*; Scott Solomon, MBA, MSE; Christine Stencel, MA; Regina Yan, MA, *Chief Operating Officer*

| AGENDA                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
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| AGENDA ITEM                                                                       | RELATED MINUTES                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Chair's Welcome<br>- <i>Grayson Norquist, MD, MSPH, Chair</i>                     | Dr. Norquist opened the meeting and welcomed the Board members present as well as the attendees, both in-person and on the phone. It was acknowledged that this would be the last meeting for Dr. Arnold Epstein who, due to his new position with HHS, was not reappointed to the Board. Dr. Epstein was thanked for his service.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Approval of the August Minutes<br>- <i>Grayson Norquist, MD, MSPH, Chair</i>      | The following motion was made and seconded:<br><br><b>Motion:</b> Approve the August 27th, 2014 Board meeting minutes.<br><br><i>Approved by a majority vote of the Board by voice vote</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Executive Director's Report<br>- <i>Joseph Selby, MD, MPH, Executive Director</i> | <p>Dr. Selby recognized this 4<sup>th</sup> Anniversary of PCORI by acknowledging its strong portfolio and sound strategic plan which have developed over these four years, all its funding accomplishments which have taken place during that time, and its evolution. He noted that PCORI's evolving future includes an emergence of themes and future high priority topics receiving a sizeable investment of funding with an earlier involvement of the SOC to make the funding process more efficient and more rapid. He further reported that the GAO Review was moving along with some upcoming additional meetings. It is anticipated that the report will be delivered to Congress in March 2015.</p> <p>He pointed out the new PCORI website, which is designed to be more flexible, more user friendly, and more interactive. It also interfaces well with the iPhone and an app is currently in development. Dr. Selby also reported work is progressing on the development of the 1<sup>st</sup> Annual PCORI Meeting to be held in Fall 2015. This will be a multi-day multi-track event with heavy involvement from engagement, science and research patient partners.</p> <p>Finally, Dr. Selby reviewed the agenda for today's meeting.</p>                                                                                                                                                                                                                                                                                                                                                      |
| Q3 Dashboard Review<br>- <i>Joseph Selby, MD, MPH, Executive Director</i>         | <p>Dr. Selby presented the Q3 Organizational Dashboard and focused on a few key areas of success (green items) and areas for future work (yellow items). The success stories Selby highlighted were: 1) a documented example of our influence on research, 2) some early results of our evaluation of the impact of engagement on our merit review process, 3) the growth of our PCORI Ambassadors program, and 4) the improved response time of our Science Help Desk.</p> <p>Dr. Selby also highlighted three yellow-flagged items on the Dashboard to highlight areas where PCORI will focus its efforts: 1) progress of research projects as measured by achievement of milestones on time, 2) delayed implementation of the Pipeline to Proposal Awards, and 3) the progress of PCORnet Phase I.</p> <p>Board members raised questions and comments, including:</p> <ul style="list-style-type: none"> <li>• Asking for more information about the timeline for reports and results, particularly from the pilot projects;</li> <li>• Supporting a plan for projects that are not meeting milestones, informed by other funders, including how to determine if research contracts should be terminated;</li> <li>• Requesting additional information about customer satisfaction with science response time to Help-Desk queries; and</li> <li>• Requesting additional metrics and policies on recruitment/accrual. For example, NHLBI has a published recruitment policy that PIs review prior to submitting an application. At the end of an initial phase, projects are reviewed and only move</li> </ul> |

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|                                                                                                                                                                                                                                    | forward into further phases if they have achieved those initial recruitment milestones.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <p>Consideration of FY 2015 Budget for Approval</p> <ul style="list-style-type: none"> <li>- <i>Joseph Selby, MD, MPH, Executive Director and Regina Yan, MA, Chief Operating Officer</i></li> </ul>                               | <p>Regina Yan and Joe Selby presented PCORI's Proposed FY2015 Budget. Key items presented included:</p> <ul style="list-style-type: none"> <li>• PCORI's proposed operating budget of \$362 million for FY2015. Program Expense will be at 75%, Program Support at 17% and Administrative Support at 8% of the total budget.</li> <li>• Categories of Program, Program Support and Administrative Support consistent with best practices used by nonprofits in their financial reporting and on the 990 nonprofit tax form.</li> <li>• A proposed staffing level for FY2015 of 217, an increase of 53 positions, most of which are in the Science department. The additional staff are needed to support the growing number of awards, the new activities in peer-review and dissemination of research results, as well as the PCORI annual conference. In FY2014, PCORI has successfully on-boarded over 70 new employees.</li> <li>• A projected funding commitment for FY2015 of \$661 million which is allocated between: 80% Research awards; 19% Infrastructure (PCORnet) awards, and 2% Engagement/Pipeline-to- Proposal awards. These levels may change based on Board of Governors (BOG) further conversations and approval. These levels will not be final until the awards are approved by the Board.</li> <li>• PCORI's expectation to have \$774 million on hand at the end of FY2015, all of which will be committed by that time for funded projects. The cash-on-hand includes funds in the PCOR Trust Fund and in the operating account with the Bank of America account.</li> <li>• For the period of FY2012 through FY2019, based on the Funding Commitment Plan that totals about \$2.6 billion, an allocation projected to be about 87% Research, 10% Infrastructure (PCORnet), and 3% Engagement awards/Pipeline-to-proposal awards.</li> </ul> <p>Board members asked questions and commented on PCORI's need for additional space given the increase in head count, PCORI's ability to onboard additional employees successfully, the possible reallocation of staff based on funding levels and how projected funding commitments in FY2018 and FY2019 were developed.</p> <p>The following motion was made and seconded:</p> <p><b>Motion:</b> Approve the proposed FY2015 Budget.</p> <p><i>Approved by majority vote of the Board by roll call vote: 20 in favor; 0 opposed.</i></p> |
| <p>Consideration of Posting for Public Comment of PCORI's Draft Proposal for Peer Review and Release of Research Findings</p> <ul style="list-style-type: none"> <li>- <i>Joseph Selby, MD, MPH, Executive Director</i></li> </ul> | <p>Continued from last month's meeting, the Board revisited the issue of posting for public comment PCORI's Draft Proposal for Peer Review of Primary Research and Public Release of Research Findings. Dr. Selby thanked the NIH officials for their comments for improvement of the document prior to public posting, and noted that their comments were carefully discussed and changes to the document were made based on them. He also noted that the public comments, which will be solicited September 15 – November 7, 2014 will be visible to all. [Public comments can be made on the PCORI <a href="#">website here.</a>]</p> <p>The following motion was made and seconded:</p> <p><b>Motion:</b> Approve posting for public comment of proposed process for Peer Review of Primary Research and Release of Research findings.</p> <p><i>Approved by a majority vote of the Board by voice vote.</i></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |

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| <p>Governance Committee Report</p> <ul style="list-style-type: none"> <li>- <i>Steve Lipstein, MHA, Chair, Governance Committee</i></li> </ul>                                                                                                                                                                                                              | <p>Mr. Lipstein reviewed recommendations given to the Board by governance consultants Marla Bobowick and Debbie Hechinger, outlining ways PCORI could enhance Board effectiveness. All recommendations since have been adopted with the exception of the establishment of an Executive Committee. The Board tasked the Governance Committee to make a recommendation as to whether an Executive Committee would facilitate and streamline the governance of PCORI.</p> <p>The committee considered PCORI's authorizing law, DC laws affecting not-for-profit associations, PCORI's open meeting policy and PCORI's Board vote history. After evaluating the merits of an Executive Committee at two meetings taking these considerations into account, the Governance Committee recommended that the PCORI Board not charter an Executive Committee at this time.</p> <p>Mr. Lipstein also informed the Board of a Guidance document approved by the Governance Committee for use in planning when voice votes or roll call votes should be used when taking action on matters by the Board. He pointed out that this document is not meant to be all-inclusive but rather a guide when deciding which vote method would be more appropriate.</p> <p>The following motion was made and seconded:</p> <p><b>Motion:</b> Approve acceptance of the recommendation of the Governance Committee that the Board not establish an Executive Committee at this time.</p> <p><i>Approved by a majority vote of the Board by voice vote.</i></p>                                                                                                                                                                                                                                                                          |
| <p><b>Lunch</b></p>                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <p>Panel Discussion with PCORnet Clinical Data Research Network (CDRN) &amp; Patient-Powered Research Network (PPRN) Principal Investigators (PI's)</p> <ul style="list-style-type: none"> <li>- <i>Thomas W. Carton, PhD, MS</i></li> <li>- <i>Rachel Hess, MD, MS</i></li> <li>- <i>Holly Peay, MS, CGC</i></li> <li>- <i>Sharon Terry, MA</i></li> </ul> | <p>The panel was composed of two Clinical Data Research Network (CDRN) Principal Investigators (Rachel Hess and Tom Carton) and two Patient-Powered Research Network (PPRN) Principal Investigators (Sharon Terry and Holly Peay). The panels represented the following CDRNs and PPRNs:</p> <p><u>CDRNs:</u></p> <ul style="list-style-type: none"> <li>- <i>Thomas W. Carton, PhD, MS</i>, CDRN Director of Analytics Louisiana Public Health Institute Principal Investigator, Louisiana Clinical Data Research Network (LACDRN)</li> <li>- <i>Rachel Hess, MD, MS</i>, CDRN Associate Professor of Medicine University of Pittsburgh School of Medicine Principal Investigator, PaTH Clinical Data Research Network</li> </ul> <p><u>PPRNs:</u></p> <ul style="list-style-type: none"> <li>- <i>Holly Peay, MS, CGC</i>, PPRN Vice President, Education and Outreach, Parent Project Muscular Dystrophy Principal Investigator, DuchenneConnect Patient-Powered Research Network</li> <li>- <i>Sharon Terry, MA</i>, PPRN President and CEO Genetic Alliance Principal Investigator, Community Engaged Network for All (CENA) Patient-Powered Research Network</li> </ul> <p>Each panelist provided an overview of their networks including key challenges and successes, partnerships, and their vision for PCORnet. The CDRN PIs presented first, followed by questions. The questions pertained to complete data, the opportunity for state money for one of the CDRNs in particular, an Individual Record Identifier, and the possibility of developing an ongoing blog to track PCORnet updates. The PPRN PIs then presented using a similar framework for discussion as the CDRNs. The final questions included how to get from today to doing research, the role of the PI, and the role of PPRNs</p> |
| <p>Review and discuss plans for Phase II of PCORnet</p>                                                                                                                                                                                                                                                                                                     | <p>Dr. Rachael Fleurence presented the initial plan for PCORnet Phase II. She discussed the plan to start Phase II in October 2015, with the funding announcement to be released in December 2014. The proposed plan included types of funding during Phase II, the tapering</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

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| <ul style="list-style-type: none"> <li>- <i>Joseph Selby, MD, MPH, Executive Director</i></li> <li>- <i>Rachael Fleurence, PhD, Program Director, CER Methods and Infrastructure Program</i></li> </ul> | <p>of infrastructure funding over the three-year duration, and expanding the number of PPRNs and CDRNs to new applicants. The discussion with Board members included the types of researchers, sustainability, benchmarks for success in Phase I, and expanding depth or breath of the network.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <p>Update on Methodology Committee Initiatives</p> <ul style="list-style-type: none"> <li>- <i>Robin Newhouse, PhD, RN, Chair, Methodology Committee</i></li> </ul>                                     | <p>Dr. Robin Newhouse provided an update on the Methodology Standards Dissemination and Implementation Plan and on the development of new methodology standards. During the discussion there was a request from the Board that the Committee provide specific examples of tools needed to assess, evaluate, and guide compliance in regard to the Methods Standards. There was also some question as to how best to eventually transfer efforts from guidance to performance measurement in order to comply with the legislative mandates. The Committee was asked by Board members to provide a timeline to accomplish the goal of curriculum development. There was a suggestion to utilize outside sources to expedite development. Additionally, there was a suggestion to structure and disseminate the coursework as part of a Massive Open Online Course (MOOC). The Committee indicated that a more developed plan and timeline will be presented at the Methodology Committee face-to-face meeting in November.</p> <p>There was also a Board request to include a formalized communication plan to include relevant stakeholders and methods of outreach to them. It was suggested that alternative parallel processes could be put into place to help ensure that the Standards curriculum is ready for dissemination within ~18 months.</p> <p>Dr. Newhouse also gave an update on the monitoring of the PCORI Methods portfolio, the committee's collaboration with the Advisory Panel on Clinical Trials, the translation framework, and the Methodology Consultation project, which will be implemented for the first round of Pragmatic Clinical Studies applications in November 2014. She presented on the role of the Methodology Committee in addressing issues regarding missing or inconsistent data. Although PCORI's Methodology Committee has developed a set of standards regarding how researchers should handle missing data in CER, these standards are meant to apply to CER studies broadly and are therefore not specific to issues arising in data networks. As a result it was felt that additional data network-specific guidance is needed. PCORI will be hosting an invitational workshop for representatives of data networks that currently conduct distributed analyses, the broad goals of which will be the identification of promising models and future research needs related to the conduct of distributed analyses in data networks. The specific goals of this day-long workshop (on either December 3 or 4 in Washington D.C.) will be to reach a shared understanding of the most promising approaches for conducting distributed analyses, identification of the methodological and technical barriers to conducting these analyses, and the identification of most important areas for future methodological research. Newhouse also informed the Board about a meeting on Decision Sciences which will be taking place in November 2014, to coincide with the November 19th Methodology Committee Face-to-Face meeting in Chicago.</p> <p>Finally, Dr. Newhouse announced that a Value of Information (VOI) RFI has been announced with the goal of collecting input from stakeholders regarding priorities for research on optimal processes for incorporating VOI into internal evaluation and research prioritization decisions. In discussing the possibility of subjecting the current PCORI portfolio to VOI analysis, it was agreed that this was an effort that could involve the Methodology Committee.</p> |
| <p>Improving Health Systems (IHS) Program Overview</p> <ul style="list-style-type: none"> <li>- <i>Steve Clauser, PhD, MPA, Program Director, IHS Program</i></li> </ul>                                | <p>Dr. Steve Clauser provided an overview of the PCORI IHS program in terms of the types of funded projects in the current portfolio, lessons learned, and goals for the next year. He presented the Broad portfolio, including types of interventions, system levels intervened, and study designs. He then presented the targeted portfolio, and the current IHS strategic framework. The presentation concluded with lessons learned from studies funded in the first two cycles, i.e. that close contract management and proactive communication with</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |

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|                                                                                                                                                                                            | <p>investigators is essential. Over the next year, the program is looking to fund larger, more impactful projects.</p> <p>It was suggested that the portfolio should consider focusing on bigger questions (e.g. restructuring of healthcare systems, like Emergency Department redesign), though it was noted that healthcare systems are extremely complex and constantly changing. The IHS program has taken steps to move toward funding larger studies with greater potential for impact (e.g., larger broad studies with \$5million/5 year maximum direct costs and duration). Clauser added that the pragmatic clinical studies announcement doubles the amount to \$10 million, an example of PCORI funding larger, more impactful studies. The Board also discussed the portfolio's definition of CER, restructured quality improvement and PCORI's vision of how CER applies to IHS.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <p>Agency for Healthcare Research &amp; Quality (AHRQ) PCOR Trust Fund Research Agenda</p> <ul style="list-style-type: none"> <li>- <i>Richard Kronick, PhD, Director, AHRQ</i></li> </ul> | <p>Dr. Richard Kronick's presentation included an overview of AHRQ and its past, present and future work in patient-centered outcomes research. AHRQ, which receives 16% of the PCOR Trust Fund, and PCORI each continue to collaborate and clarify the focus of their work. PCORI and AHRQ should collaborate, complement and not duplicate work. Overall, AHRQ is an evidence-producing organization that aims to make healthcare better for patients.</p> <p>AHRQ is charged with training health services researchers and broadly disseminating research findings. Dissemination/translation activities funded by the PCOR Trust Fund fall into four categories including training, systematic review development and updates, research translation, and large broad-based implementation and dissemination activities. The greatest challenge is dissemination and implementation of PCOR in a way we know really works. Therefore, AHRQ is moving to projects where the evidence presented and disseminated will show a direct impact on changing practice.</p> <p>Moving forward, AHRQ's work in PCOR has pivoted to dissemination and training. Kronick stated that collaboration between AHRQ and PCORI is key to increasing the use of evidence-based research in decision making and translation into clinical practice. With regard to the field in general, scalability and generalizability is essential but very challenging because these are very complex projects.</p> <p>The similarities and differences between the two presentations were discussed. It was suggested that there is a need for incentivized effective changes in dissemination, which either PCORI or AHRQ could take on.</p> |
| <p>Public Comment</p> <ul style="list-style-type: none"> <li>- <i>Susan Sheridan, MBA, MIM, Director, Patient Engagement</i></li> </ul>                                                    | <p>The Chair opened the meeting to public comment, inviting comments from those attending the meeting in person and those attending remotely. Contributing with comments was:</p> <ul style="list-style-type: none"> <li>- Sara van Geertruyden, Partnership to Improve Patient Care (PIPC)</li> </ul> <p>The Board agreed to include an additional earlier section in the agenda for public comment in future meetings.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <p>Wrap-up and Adjournment of the Meeting of the Board</p> <ul style="list-style-type: none"> <li>- <i>Grayson Norquist, MD, MSPH, Chair</i></li> </ul>                                    | <p>The meeting was adjourned at 5:15 pm.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |

**Approved by the PCORI Board of Governors 11-18-2014**