

## Board of Governors Meeting via Teleconference / Webinar

Tuesday, June 21, 2016

12:00 pm – 1:30 pm ET

### Board Members Present:

Grayson Norquist, MD, MSPH, *Chairperson*; Debra Barksdale, PhD, RN; Larry Becker; Andy Bindman, MD; Michael Lauer, MD (designee for Francis Collins, MD, PhD); Allen Douma, MD; Leah Hole-Marshall, JD; Gail Hunt; Sharon Levine, MD; Freda Lewis-Hall, MD; Barbara McNeil, MD, PhD; Harlan Weisman, MD; Robert Zwolak, MD, PhD;

### Board Members Absent:

Kerry Barnett, JD, *Vice Chairperson*; Alicia Fernandez, MD; Christine Goertz, DC, PhD; Robert Jesse, MD, PhD; Harlan Krumholz, MD, SM; Richard Kuntz, MD, MSc; Steve Lipstein, MHA; Ellen Sigal, PhD

## Minutes

| Agenda Item                                                                                                                                                                                                     | Related Minutes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
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| Call to Order, Roll Call, and Welcome <ul style="list-style-type: none"> <li>- Grayson Norquist, MD, MSPH, <i>Chairperson</i> and Joe Selby, MD, MPH, <i>Executive Director</i></li> </ul>                      | Dr. Norquist chaired and opened the meeting, welcomed all to the meeting of the PCORI Board of Governors and read the Chair Statement on Conflict of Interest.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Consider for Approval:</b><br>Minutes of the May 23, 2016 Board Meeting <ul style="list-style-type: none"> <li>- Grayson Norquist, MD, MSPH</li> </ul>                                                       | The following motion was made by Larry Becker and seconded by Harlan Weisman:<br><br><b>Motion:</b> Approve the minutes of the May 23, 2016 Board of Governors meeting.<br><br><i>Approved by a majority vote of the Board by voice vote (no opposed; no abstentions)</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Consider for Approval:</b><br>PCORnet Initiative on Health Plan/System Data Partnership Awards (A Stepwise Approach to Collaboration) <ul style="list-style-type: none"> <li>- Joe Selby, MD, MPH</li> </ul> | Dr. Selby introduced the request for funding of the slate of awards for the PCORnet Initiative on Health Plan/System Data Partnerships (A Stepwise Approach to Collaboration). He presented a brief overview of completed data efforts, the purpose of the initiative, and application evaluation criteria. He also discussed the review process and highlighted key components of the two projects recommended for funding based on the review criteria and the total proposed budgets for each. During the presentation, he addressed questions around the interoperability of the health plans with PCORnet-related entities, core data elements being captured during the proposed projects, and updates on the CMS pilot project, ADAPTABLE, and the PCORnet Commons. It was noted that during its June 20, 2016 meeting, the Research Transformation Committee |

Limited PCORI 2016 Funding Announcement: Health Systems Interactions Demonstration Research Projects

- Joe Selby, MD, MPH

(RTC) recommended the funding of the awards on the slate (*See Attachment A for slate summary*).  
The following motion was made by Sharon Levine and seconded by Larry Becker:

**Motion:** Approve funding for the Health Plan Infrastructure Awards.

Approved by a majority vote of the Board members by roll call (13 in favor, 0 opposed, 0 abstentions)

Dr. Joe Selby presented the request for funding of the slate of awards for Health Systems Interactions Demonstration Research Projects. He presented a brief overview of the purpose and goals of the funding announcement. He emphasized that the focus of these demonstration research projects is on the needs of learning healthcare systems to support improved decision-making and learning by health systems, care providers, patients and families and to evaluate PCORnet's capacity to support collaborative research, and thus these demonstration research projects are not solely comparative effectiveness research projects. He also outlined the relationship of these research projects to the evolution of the PCORnet Sustainability Plan and the importance of health systems in its support, and summarized the application review criteria. He also discussed the application review process and gave an overview of each of the proposed projects, including the proposed total budget for the slate. During the presentation, he addressed questions around the dissemination of project results and the peer review process, the replicability of study designs, and the appropriateness of study aims for one of the applications proposed for funding. It was noted that during its June 15, 2016 meeting the Selection Committee (SC) recommended the funding of these awards (*See Attachment B for slate summary*).

The following motion was made by Larry Becker and seconded by Bob Zwolak:

**Motion:** Approve funding for the Health Systems PCORnet Research Demonstration Projects.

Approved by a majority vote of the Board members by roll call (9 in favor; 1 opposed (Leah Hole-Marshall); 1 abstained (Andrew Bindman); 2 recusals (Freda Lewis-Hall and Barbara McNeil. Ellen Sigal earlier

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|                                                                                                            | <i>announced her intention to recuse, but was not present at the meeting.)</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Consider for Approval:</b><br>Staff recommendation for Hepatitis C Targeted PFA<br>- Joe Selby, MD, MPH | <p>Dr. Selby presented staff recommendations on a possible funding announcement for studies of immediate versus delayed treatment for Hepatitis C. Dr. Selby reviewed the chronology of PCORI-related activities related to Hepatitis C.</p> <p>The original PCORI multi-stakeholder meeting on this topic took place in October 2014. In December 2014, the PCORI Board approved the development of Hepatitis C targeted Funding Announcement covering 4 questions for a commitment of up to \$50 million, which was informed by the October 2014 Stakeholder meeting. The original Hepatitis C targeted funding announcement was released by PCORI in February 2015.</p> <p>In September 2015, the Board approved the award of 2 Hepatitis C research projects for a total of \$29 million, including a study on alternative ways to deliver care to high risk populations and a head-to-head comparison of new therapies.</p> <p>In March 2016, the Board was provided with an update on the status of the targeted PFA and informed that the Science Oversight Committee had endorsed the re-release of the Hepatitis C targeted PFA with two revised research questions, which included the randomized trial on immediate versus delayed treatment. Following the March 2016 Board meeting, stakeholders expressed concerns with using randomized trials to test active surveillance for Hepatitis C. PCORI re-convened the multi-stakeholder stakeholder meeting in May 2016 to revisit the funding announcement.</p> <p>Dr. Selby explained that during the second stakeholder meeting, many voiced concerns that the proposed study's one-year length was too long, delaying access to treatment, while others, noted that a shorter study length would limit the outcomes that could be measured. Many stakeholders discussed the potential for ethical issues of active surveillance in disadvantaged populations.</p> <p>Based on the low practical value of the proposed study for guiding practice, substantial concerns about the feasibility of such a study, challenges related to</p> |

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|                                                                                                                                         | <p>interpreting the results, and ethical concerns voiced by many, Dr. Selby indicated that the PCORI staff recommended not to proceed with posting a funding announcement on this topic. PCORI staff also recommended that the other revised Hepatitis C question from the March 2016 funding announcement related to an observational study on screening and diagnosis not proceed due to feedback from the May 2016 stakeholder meeting.</p> <p>The Board of Governors considered the results of the stakeholder meeting and weighed the potential quality and impact of the evidence that would be generated by research that would be conducted under this funding announcement. Board members discussed the role of PCORI.</p> <p>In response to questions from the Board, Dr. Selby confirmed that the staff recommendation to not proceed with posting a funding announcement for a study on the short-term outcomes of delayed vs. immediate treatment of Hepatitis C included not proceeding with either a randomized, placebo controlled trial or an observational study.</p> <p><i>The following motion was made by Sharon Levine and seconded by Andy Bindman:</i></p> <p><b><i>Motion:</i></b> Approve staff recommendation to NOT proceed with posting a funding announcement for a study on the short-term outcomes of Delayed vs. Immediate treatment of Hepatitis C.</p> <p><i>Approved by a majority vote of the Board members by roll call (10 in favor, 1 opposed (Leah Hole-Marshall); 0 abstentions; 0 recusals) Michael Lauer and Gail Hunt were not present during the vote on this agenda item.</i></p> |
| <p>Report on Research Synthesis</p> <ul style="list-style-type: none"> <li>- Evelyn Whitlock, MD, MPH, Chief Science Officer</li> </ul> | <p>This agenda item was tabled for a later meeting</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <p>Wrap up and Adjournment</p> <ul style="list-style-type: none"> <li>- Grayson Norquist, MD, MSPH</li> </ul>                           | <p>The meeting adjourned at 1:34 pm</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |

**Minutes were approved by the PCORI Board of Governors 07-19-2016**

**Additional Materials: Attachments A and B****ATTACHMENT A****Approved Slate of Awards:****PCORnet Initiative on Health Plan/System Data Partnerships (A Stepwise Approach to Collaboration)**

| <b>Health Plan Data Project*</b> | <b>Total Budget</b> |
|----------------------------------|---------------------|
| 1 HealthCore-Anthem Research     | \$5.20M             |
| 2 Project Data Link-Humana       | \$3.70M             |

\*Titles of the awarded Health Plan Infrastructure Awards have been added to the minutes to document the awards, but were not made available to the Board at the Board meeting given that they included identifying information.

## ATTACHMENT B

### Approved Slate of Awards:

#### Health Systems Interactions Demonstration Research Projects

| Project Title                                                                                             | Total Budget |
|-----------------------------------------------------------------------------------------------------------|--------------|
| Identifying and Predicting Patients with Preventable High Utilization                                     | \$1.20M      |
| Automating Quality and Safety Benchmarking for Children: Meeting the Needs of Health Systems and Patients | \$0.7M       |
| The Impact of Patient Complexity on Healthcare Utilization                                                | \$1.00M      |