



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Board of Governors Meeting via Teleconference / Webinar

Tuesday, August 15, 2017

12:00 pm – 1:30 pm ET

Board Members Present:

Robert Zwolak, MD, PhD, *Acting Chairperson*; Debra Barksdale, PhD, RN; Larry Becker; Francis Collins, MD, PhD; Allen Douma, MD; Alicia Fernandez, MD; Leah Hole-Marshall, JD; Russell Howerton, MD; Gopal Khanna; Sharon Levine, MD; Barbara McNeil, MD, PhD; Ellen Sigal, PhD; Kathleen Troeger, MPH

Board Members Absent:

Grayson Norquist, MD, MSPH, *Chairperson*; Kerry Barnett, JD, *Vice Chairperson*; Christine Goertz, DC, PhD; Gail Hunt; Robert Jesse, MD, PhD; Harlan Krumholz, MD, SM; Richard Kuntz, MD, MSc; Freda Lewis-Hall, MD

MINUTES

Agenda Item	PCORI Speakers
Call to Order, Roll Call, and Welcome - Robert Zwolak, MD, PhD, <i>Acting Chairperson</i> and Joe Selby, MD, MPH, <i>Executive Director</i>	Dr. Zwolak served as Acting Chairperson for this meeting. He opened the meeting, thanked all who joined the call and welcomed all to the meeting of the PCORI Board of Governors. He then read the Chair Statement on Conflict of Interest. Dr. Selby reviewed the agenda for the meeting.
Consider for Approval: Consent Agenda • Minutes of the July 18, 2017 Board Meeting • Nomination for Committee Appointment - Robert Zwolak, MD, PhD	Dr. Zwolak introduced the Consent Agenda which included the approval of the July 18, 2017 meeting minutes, and approval of the nomination by the Governance Committee of Gopal Khanna, PCORI's newest Board member and Director of AHRQ, to serve on the Engagement, Dissemination, and Implementation Committee (EDIC). Dr. Zwolak gave the opportunity to Board members to discuss any of the matters on the Consent Agenda. No separate discussion was requested. The following motion was presented for Board approval: That the Board approve: • Minutes from the July 18, 2017 Board meeting • Nomination by the Governance Committee of Board Member Gopal Khanna to serve on the Engagement, Dissemination, and Implementation Committee (EDIC). Motion: Approve the Motion for Consent Agenda Items <i>Approved by a majority vote of the Board by voice vote (no opposed; no abstentions)</i>
Consider for Approval: • New Advisory Panelists - Evelyn Whitlock, MD, MPH, <i>Chief Science Officer</i>	Dr. Whitlock presented the 2017 proposed slate of new panelists, alternates, reappointments and co-chairs for all seven of PCORI's Advisory Panels: Addressing Disparities (AD); Assessment of Prevention, Diagnosis and Treatment Options (APDTO); Clinical Trials (CTAP); Communication and Dissemination Research (CDR); Improving Healthcare Systems (IHS); Patient Engagement (PEAP); and Rare Disease (RDAP). This year, 151 applications were received which underwent a rigorous vetting process and an effort to create a balanced slate representing a variety of group interests. The Board

	was presented with proposed slates of panelists, terms and other positions for each Advisory Panel for approval as reflected in Attachment A to these minutes; 26 new panelists, 4 alternates, 7 reappointments and 1 co-chair appointment. <i>The following motion was made by Larry Becker and seconded by Barbara McNeil:</i> Motion: Approve the proposed slates of members, positions and terms for the following Advisory Panels: APDTO, IHS, AD, PEAP, CTAP, RDAP and CDR <i>Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions)</i> Board members thanked former panelists and welcomed all appointed members and alternates to the respective Advisory Panels. (See Attachment A for list of Advisory Panel members, positions and terms approved).
Consider for Approval: Proposed Slate for Cycle 3, 2016 Broad PFA Awards - Christine Goertz, DC, PhD, Chair, Selection Committee, Leah Hole-Marshall, JD, Vice-Chair, Selection Committee and Evelyn Whitlock, MD, MPH	Dr. Selby noted that today's agenda included slates of awards recommended by the Selection Committee to the Board for approval for the Broad PFA Cycle and two targeted PFAs, one related to Opioid Prescribing and one related to Palliative Care. He acknowledged the hard work and dedication of staff, applicants and Board committees to these initiatives over the past year. Dr. Whitlock began the presentation of the proposed slate for the Cycle 3, 2016 Broad PFA awards by providing a budget overview of the slates to be considered for approval at today's meetings as well as the slates for approval that is expected to be presented to the Board at the September 12, 2017 Board meeting. She pointed out that the approval request for today's applications are \$4.4M in excess of the budget, but during the meeting on September 12, the slates that are expected to be presented will likely be below budget and therefore the cumulative is expected to be less than the maximum budget. Dr. Whitlock continued by noting 236 Letters of Intent (LOIs) were received and 151 LOIs were invited to submit full proposals (64%). Of the 151 LOIs, 115 applications were received (76% of invited LOIs), for an overall funding rate of 13%. The Board was asked to consider funding 15 applications which address five national priority areas. . Seven applications are resubmissions, representing 47%. The Broad slate consists of 15 research projects, as identified on Attachment B to these minutes, across Addressing Disparities (2 recommended projects); Assessment of Prevention, Diagnosis, and Treatment Options (4 recommended projects); Communication and Dissemination Research (1 recommended project); Improving Healthcare Systems (4 recommended projects); and Improving Methods for Conducting PCOR (4 recommended projects). The proposed total award for this slate is \$36 million. Leah Hole-Marshall, Vice Chair of the Selection Committee, thanked all the applicants and congratulated those recommended for funding. <i>(See Attachment B for the list of Cycle 3, 2016 Broad PFA projects funded.)</i>

	<i>The following motion was made by Debra Barksdale and seconded by Sharon Levine:</i> Motion: Approve funding for the recommended slate of awards from the Cycle 3, 2016 Broad PFAs. <i>Approved by a majority vote of the voting Board members by roll call (10 in favor; 0 opposed; 0 abstentions and 3 recusals, Alicia Fernandez, Barbara McNeil and Robert Zwolak)</i> <i>(See Attachment B for the list of Cycle 3, 2016 Broad PFA research projects approved for funding.)</i>
Consider for Approval: Proposed Slate for Cycle 3, 2016 Targeted PFA Award • Strategies to Prevent Unsafe Opioid Prescribing in Primary Care among Patients with Acute or Chronic Non-Cancer Pain - <i>Christine Goertz, DC, PhD; Leah Hole-Marshall, JD and Evelyn Whitlock, MD, MPH</i>	Dr. Whitlock introduced the proposed awards for the targeted PFA seeking to determine Strategies to Prevent Unsafe Opioid Prescribing in Primary Care among Patients with Acute or Chronic Non-Cancer Pain. . Of the 35 Letters of Intent (LOI) submitted, 20 LOIs were invited to submit a full application (57%). A total of 12 applications were received (60% of invited LOIs). The Selection Committee reviewed the proposed slate and proposed funding two applications (identified on Attachment C to these minutes) of the 12 received. These complementary but distinct applications include a proposed budget of \$9.8 million of the \$30M allotted for this PFA. The first research project is a naturalistic experiment evaluating the impact Medicaid treatment reimbursement changes on opioid prescribing and patient outcomes among patients with low back pain. The total research project cost is \$5.7M with a research project duration of three years. The second research project aim is provider-targeted behavioral interventions to prevent unsafe opioid prescribing for acute non-cancer pain in primary care. The total research project cost is \$4.2M with a project duration of three years. The Board noted that it is exciting to see research projects proposed for funding in the important and urgent need around opioid prescribing. Leah Hole-Marshall noted that additional opioid related awards are expected to be proposed for funding at the next Board meeting scheduled for September 12. <i>The following motion was made by Francis Collins and seconded by Larry Becker:</i> Motion: Approve funding for the recommended slate of awards from the Cycle 3, 2016 Strategies to Prevent Unsafe Opioid Prescribing in Primary Care among Patients with Acute or Chronic Non-Cancer Pain PFA. <i>Approved by a majority vote of the voting Board members by roll call (10 in favor; 0 opposed; 0 abstentions and 2 recusals, Sharon Levine and Barbara McNeil); Russell Howerton was not present during this vote.</i> <i>(See Attachment C for the list of Cycle 3, 2016 Targeted PFA research projects approved for funding.)</i>

Consider for Approval: Proposed Slate for Cycle 3, 2016 Targeted PFA Award • Community-Based Palliative Care Delivery for Adult Patients with Advanced Illnesses and their Caregivers - <i>Christine Goertz, DC, PhD; Leah Hole-Marshall, JD and Evelyn Whitlock, MD, MPH</i>	Dr. Whitlock introduced the final proposed slate for the Community-Based Palliative Care Delivery for Adult Patients with Advanced Illnesses and their Caregivers Cycle 3, 2016 Targeted PFA. The objective of the PFA on community-based palliative care delivery was to fund multiple, large, multi-site, comparative effectiveness research (CER) studies aimed at facilitating the delivery of community-based palliative care emphasizing advance care planning and models of care delivery. Of the 52 Letters of Intent, 39 were invited to submit a full application (75%). A total of 31 applications were received (79% of invited LOIs). The Selection Committee reviewed the proposed slate which proposed funding seven applications (identified on Attachment C to these minutes) of the 31 received for a budget of \$73.7M of the allotted \$48M for this PFA. It was noted by Dr. Whitlock that these research projects address unmet needs in the area of palliative care, focusing on large, multi-site community-based facilities across 24 states. Dr. Whitlock concluded by summarizing the budget overview of the remainder of fiscal year 2017 which ends September 30, 2017, for funding Cycle 3, 2016 PFAs. Between today's proposed applications and those that are expected to be presented at the September 12 meeting, the total budgeted amount is \$249M, and the proposed/estimated total budget is \$223.8M. <i>The following motion was made by Larry Becker and seconded by Kathleen Troeger:</i> Motion: Approve funding for the recommended slate of awards from the Cycle 3, 2016 Community-based Palliative Care Delivery for Adult Patients with Advanced Illnesses and their Caregivers PFA. <i>Approved by a majority vote of the voting Board members by roll call (9 in favor; 0 opposed; 0 abstentions and 3 recusals, Alicia Fernandez, Sharon Levine and Barbara McNeil); Russell Howerton was not present during this vote.</i> <i>(See Attachment C for the list of research projects approved for funding in response to this PFA.)</i>
Wrap up and Adjournment - <i>Robert Zwolak, MD, PhD</i>	Meeting ended at 1:23 pm

Minutes were approved by the PCORI Board of Governors 09-12-2017

[See attached for:](#)

[Attachment A: List of Advisory Panel panelists approved](#)

[Attachment B; List of Cycle 3, 2016 Broad PFA Awards approved](#)

[Attachment C: List of Cycle 3, 2016 Targeted PFA Awards approved](#)

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MINUTES – Attachment A

MEMBERS, POSITIONS AND TERM APPROVED FOR 7 PCORI ADVISORY PANELS

*Proposed panelists that were nominated by a third party organization have been marked with an asterisk

Addressing Disparities:

Name	Stakeholder Group	Term (in Years)
Nadine Barrett*	Hospital/Health System	3
Cheryl Holly	Researcher	3
Mary Grace Pagaduan	Patient/ Caregiver/ Patient Advocate	3
Alternate Candidate		
Sumedha Chhatre	Researcher	3

Assessment of Prevention, Diagnosis, and Treatment Options:

Name	Stakeholder Group	Term (in Years)
Lawrence Goldberg	Clinician	3
Melissa Hicks	Patient/Caregiver/ Patient Advocate	3
Robin Karlin	Patient/Caregiver/ Patient Advocate	3

Clinical Trials:

Name	Stakeholder Group	Term (in Years)
Jacqueline Halladay	Researcher	3
Elisa Hurley	Training Institution	3
Hartley Jones	Patient/Caregiver/Patient Advocate	3
Richard Page	Clinician	3
Andrea Troxel*	Researcher	3

F. Todd Wetzel*	Clinician	3
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Communication and Dissemination Research:

Name	Stakeholder Group	Term (in Years)
Reappointed Members		
Nancy Blake	Clinician	3
Neela Goswami	Researcher	3
Helen Osborne	Patient/Caregiver/ Patient Advocate	3
Ruth Parker	Patient/Caregiver/ Patient Advocate	3
Andrew Rosenberg	Patient/Caregiver/ Patient Advocate	3
Sandi Smith	Researcher	3
Cornell Wright	Policy Maker	3

Improving Healthcare Systems:

Name	Stakeholder Group	Term (in Years)
Danielle Brooks	Industry	3
Rachel Raia	Payer	3
James Wharam	Researcher	3
Alternate Candidate		
Mary Kathleen Kenyon	Patient/ Caregiver/ Patient Advocate	3

Patient Engagement:

Name	Stakeholder Group	Term (in Years)
Sonya Ballentine	Patient/Caregiver/ Patient Advocate	3
Katherine Capperella	Industry	3
Brendaly Rodriguez	Patient/Caregiver/ Patient Advocate	3
Beverly Rogers	Patient/Caregiver/Patient Advocate	3
Thomas Scheid	Patient/Caregiver/ Patient Advocate	3

Norah Schwartz	Researcher	3
Freddie White-Johnson	Patient/Caregiver/ Patient Advocate	3
Alternate Candidates		
David Andrews	Patient/Caregiver/ Patient Advocate	3
Betty Scull	Patient/Caregiver/ Patient Advocate	3
New Co-Chair		
David White	Patient/ Caregiver/ Patient Advocate	1

Rare Disease:

Name	Stakeholder Group	Term (in Years)
Julie Abramson	Patient/Caregiver/ Patient Advocate	3
Cindy Luxhoj	Patient/Caregiver/ Patient Advocate	3
Stephen Mathai*	Researcher	3
Marcia Rupnow	Industry	3

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MINUTES – Attachment B

Cycle 3, 2016 Broad PFA Slate Approved

Program	Project Title
Addressing Disparities	Culturally Sensitive, Primary Care Clinic-Based Interventions by Community Health Workers and Trained Physicians to Promote and Sustain Weight-Loss among Black Women Patients with Obesity
	Comparing the Effectiveness of House Calls and Peer Mentorship to Reduce Racial Disparities in Live Donor Kidney Transplantation
Assessment of Prevention, Diagnosis, and Treatment Options	Prospective Multicenter Observational Cohort Study of Comparative Effectiveness of Disease-Modifying Treatments for Myasthenia Gravis (MG)
	Study of Radiation Fractionation on Outcomes After Breast REConstruction (FABREC)
	Real World Effectiveness and Safety of Hysteroscopic Compared to Laparoscopic Sterilization
	Non-Pharmacologic Approaches to Relieve Pain and Symptom Distress among Diverse Hospitalized Cancer Patients
Communication and Dissemination Research	Engaging Parents of Children with Sickle Cell Anemia and their Providers in Shared-Decision Making for Hydroxyurea
Improving Healthcare Systems	Leveraging Integrated Models of Care to Improve Patient-Centered Outcomes for Publicly-Insured Adults with Complex Health Care Needs
	Comparing Patient-Centered Outcomes of Standardized vs Patient-Driven Diabetes Shared Medical Appointments
	A Multi-Center Randomized Controlled Trial of Perioperative Palliative Care Surrounding Cancer Surgery for Patients and their Family Members (the PERIOP-PC Trial)
	Optimizing Care for Patients with Dementia: A Comparison of Two Non-Pharmacological Treatment Approaches
Improving Methods for Conducting PCOR	Statistical Methods and Designs for Addressing Correlated Errors in Outcomes and Covariates in Studies Using Electronic Health Records Data
	Develop Novel Design Methods for Pragmatic Stepped-Wedge Cluster Trials with Patient-Centered Outcomes
	Causal Analyses of Nested Case-Control Studies for Comparative Effectiveness Research
	“Randomize Everyone”: Creating Valid Instrumental Variables for Learning Health Care Systems

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MINUTES – Attachment C

Cycle 3, 2016 Targeted PFA Slate Approved

Strategies to Prevent Unsafe Opioid Prescribing in Primary Care among Patients with Acute or Chronic Non-Cancer Pain PFA

Awarded Projects
A Naturalistic Experiment Evaluating the Impact of Medicaid Treatment Reimbursement Changes on Opioid Prescribing and Patient Outcomes among Patients with Low Back Pain
Provider-Targeted Behavioral Interventions to Prevent Unsafe Opioid Prescribing for Acute Non-Cancer Pain in Primary Care

Community-Based Palliative Care Delivery for Adult Patients with Advanced Illnesses and their Caregivers

Awarded Projects
A Non-Inferiority Comparative Effectiveness Trial of Physician-Led vs. Nurse-Led Home-Based Palliative Care in Older Adults with Advanced Illness and Their Family Caregivers
Population-Based Comparison of Evidence-Based, Patient-Centered Advance Care Planning Interventions on Advance Directive Completion, Goal Concordant Care and Caregiver Outcomes for Patients with Advanced Illness
Reducing Disparities in the Quality of Palliative Care for Older African Americans through Improved Advance Care Planning (EQUAL ACP)
Introducing Palliative Care within the Treatment of End Stage Liver Disease: A Randomized Controlled Trial
A Cluster-Randomized Trial Comparing Team-Based versus Primary Care Clinician-Led Advance Care Planning in Practice-Based Research Networks
Emergency-Department Initiated Palliative Care in Older Adults with Advanced Illness
Comparative Effectiveness of Early Integrated Telehealth versus In-Person Palliative Care for Patients with Advanced Lung Cancer