

Board of Governors Meeting via Teleconference / Webinar

Tuesday, July 27, 2021

1:00-2:30 pm Eastern

MINUTES

Board Members Present:

Christine Goertz, DC, PhD, *Chairperson*; Sharon Levine, MD, *Vice Chairperson*; Kara Ayers, PhD; Kate Berry; Michael Lauer, MD (designee for Francis Collins, MD, PhD); Jennifer DeVoe, MD, DPhil; Alicia Fernandez, MD; Christopher Frieze, PhD, RN; Russell Howerton, MD; James Huffman; Connie Hwang, MD, MPH; Barbara McNeil, MD, PhD; David Meyers, MD; Eboni Price-Haywood, MD, MPH; James Schuster, MD, MBA; Ellen Sigal, PhD; Kathleen Troeger, MPH; Danny van Leeuwen, MPH, RN; Robert Zwolak, MD, PhD

Board Members Absent: Tanisha Carino, PhD; Mike Herndon, DO; Michelle McMurry-Heath, MD, PhD; Janet Woodcock, MD

Agenda Item	PCORI Speakers
Welcome and Call to Order Consider for Approval: - Minutes of the June 15, 2021 Board Meeting - Christine Goertz, DC, PhD, Board Chairperson	Dr. Goertz 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. She then reviewed the meeting agenda. With no additions or corrections to the minutes offered, Goertz then presented the minutes of the June 15, 2021 Board meeting for approval. <i>The following motion was made by Barbara McNeil and seconded by Michael Lauer:</i> Motion: Approve the Minutes of the June 15, 2021 Board Meeting <i>Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions).</i>
Consider for Approval: Cycle 3 2020 Research and Dissemination & Implementation Award Slates Nakela L. Cook, MD, MPH, Executive Director; Barbara McNeil, MD, PhD, Chair, Selection Committee and Sharon Levine, MD, Vice Chair,	Dr. Cook began the presentation by providing an overview of the three Research award slates (<i>Attachment A</i>) and one Dissemination & Implementation award slate (<i>Attachment B</i>) being presented to the Board for approval with a total funding amount of \$255M. Cook reviewed the status of letters of intent (LOIs), applications, and funding rate relating to each of the four award slates being presented to the Board for approval, in context of historical average and upcoming slates. This is the first slate from the first cycle of Phased Large Awards for Comparative Effectiveness Research (PLACER) PFA,

<i>Engagement, Dissemination, and Implementation Committee</i>	so we have no historical data for comparison. It is, however, closest for comparison to the Pragmatic Clinical Studies PFA which on average since inception has yielded a similar rate of about 4 or 5 studies. Cook addressed the proposed research commitments in the context of the FY2021 Commitment Plan, noting that the FY2021 commitment target for research and dissemination and implementation awards is \$380M. With three slates of research awards and one slate of dissemination and implementation awards under consideration today, the cumulative FY2021 funding is \$362M. Board members expressed interest in how PCORI is making progress on its Commitment Plan, compared to the previous year. Cook discussed that in FY2021 and the prior year, PCORI has been close to meeting targets. She added the context that in FY2021, PCORI has been ramping up to its planned FY 2022 and FY 2023 peak years for award commitments. Dr. McNeil then made introductory remarks on behalf of the Selection Committee, noting that the Committee met on June 30 and July 16, 2021, and recommends three slates of Research awards for Board approval. She then introduced PCORI staff to present the slates.
Phased Large Awards for Comparative Effectiveness Research (PLACER) PFA - <i>Barbara McNeil, MD, PhD, Chair, Selection Committee</i> - <i>Anne Trontell, MD, Associate Director, Clinical Effectiveness and Decision Science (CEDS)</i>	Dr. Trontell introduced the proposed slate of awards for the Cycle 3 2020 Phased Large Award for Comparative Effectiveness Research (PLACER) PFA (see <i>Attachment A</i>). These awards support large scale, high impact, randomized trials in comparative effectiveness research. She outlined the parameters for the funded PLACER research projects, including total allocated funds, total direct costs (and total costs for the feasibility phase and the full-scale study phase) and the total research project duration (and the duration of the feasibility phase and the full-scale study phase). The Selection Committee recommended to fund a slate of 5 research projects for a proposed total commitment of \$135M. Trontell noted that continued PCORI funding for the full-scale study phase for each PLACER research project is dependent on the feasibility phase. Trontell reviewed key elements of each research project on the proposed slate, and also noted the wide variety of research topics within the proposed research projects. In response to questions from Board members, Trontell: indicated that the review criteria for PLACER PFA applications were the existing PCORI criteria with additional factors focused on PLACER funding initiative priorities, including relating to data coordination and feasibility; and, that the research project

	focused on prevention of suicide attempts would complement the proposed research projects that are part of the slate on Suicide Prevention. Dr. Cook confirmed that PCORI will be considering which research projects on the PLACER slate may be well-suited to capture a range of outcomes data relating to burdens and economic impacts. <i>The following motion was made by Michael Lauer and seconded by Kara Ayers:</i> Motion: Approve funding for the recommended slate of awards from the Cycle 3 2020 Phased Large Awards for Comparative Effectiveness Research (PLACER) PFA <i>Approved by a majority vote of the voting Board members by voice vote: none opposed, none abstained, 6 recused (Jennifer DeVoe, Christopher Friese, Christine Goertz, Russell Howerton, Sharon Levine, Barbara McNeil).</i>
Suicide Prevention: Brief Interventions for Youth Targeted PFA - Elisabeth (Els) Houtsmuller, PhD, Associate Director, Healthcare Delivery and Disparities Research (HDDR)	Dr. Houtsmuller then introduced the proposed slate of awards for the Cycle 3 2020 Suicide Prevention: Brief Interventions for Youth PFA (see <i>Attachment A</i>). She outlined the parameters for the PFA, including total allocated funds, total direct costs per research project, and the total research project duration. The Selection Committee recommended funding a slate of 4 research projects for a proposed total commitment of \$37M. Houtsmuller noted the importance of the focus into the four populations highlighted within the proposed studies. It was noted that the research project on comparison of suicide prevention interventions for youth on the autism spectrum overlaps with the intellectual and developmental disabilities research priority in PCORI's reauthorizing law. <i>The following motion was made by Barbara McNeil and seconded by Russell Howerton:</i> Motion: Approve funding for the recommended slate of awards from the Cycle 3 2020 Suicide Prevention: Brief Interventions for Youth PFA <i>Approved by a majority vote of the voting Board members by voice vote: none opposed, none abstained, 1 recused (Christine Goertz). Ellen Sigal was not present during this vote.</i>
Broad PFAs - Steve Clauser, PhD, MPA, Program Director, HDDR;	Dr. Goertz introduced Dr. Clauser, Dr. Ip and Dr. Ramsawh to provide information regarding the proposed slate of Cycle 3 2020 Broad PFA awards being presented to the Board for approval (see <i>Attachment</i>

<i>Holly Ramsawh, PhD, Senior Program Officer, CEDS; Stanley Ip, MD, Interim Program Director, CEDS</i>	A). These research projects were reviewed by the Selection Committee and recommended for Board approval. The slate consists of nineteen research projects from four different priority areas: Addressing Disparities (8 recommended research projects), Assessment of Prevention, Diagnosis, and Treatment Options (2 recommended research projects), Improving Healthcare Systems (3 recommended research projects), and Improving Methods for Conducting PCOR (6 recommended research projects). It was noted that some of the proposed research projects overlap with the research priorities of intellectual and developmental disabilities and maternal mortality in PCORI’s reauthorizing law. This slate represents a proposed total commitment of \$82M. <i>The following motion was made by Barbara McNeil and seconded by Daniel van Leeuwen:</i> Motion: Approve funding for the recommended slate of awards from the Cycle 3 2020 Broad PFAs <i>Approved by a majority vote of the voting Board members by voice vote: none opposed, none abstained, 6 recused (Michael Lauer, Alicia Fernandez, Christopher Friese, Christine Goertz, Barbara McNeil, James Schuster). Ellen Sigal was not present during this vote.</i>
Limited Competition Dissemination and Implementation PFA - <i>Sharon Levine, MD, Vice Chair, Engagement, Dissemination and Implementation Committee</i> - <i>Joanna Siegel, ScD, Program Director, Engagement, Dissemination and Implementation</i>	Dr. Levine made introductory remarks on behalf of the Engagement, Dissemination, and Implementation Committee, noting that at its June meeting, the committee discussed and voted to recommend that the Board approve the Limited Competition funding slate. She then introduced Dr. Siegel to provide details on the slate. Siegel provided a brief overview of the Limited Competition funding announcement which provides awardee teams, who have completed a PCORI-funded study, the opportunity to take the next steps in promoting uptake of the evidence into practice. The implementation project on the slate, “Implementing an Intervention to Address Concerns of Older Patients with Cancer Receiving Chemotherapy and their Caregivers”, is proposing to implement findings from a study funded through PCORI’s Communication and Dissemination Research priority area. The total funds requested for the proposed slate is \$1.4M. <i>The following motion was made by Sharon Levine and seconded by Barbara McNeil:</i>

	Motion: Approve funding for the recommended award slate from the Cycle 3 2020 Limited Competition Dissemination and Implementation PFA <i>Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions). Ellen Sigal was not present during this vote.</i>
Strategic Planning Update - Nakela L. Cook, MD, MPH and Sharon Levine, MD, Co-Chairs, Strategic Planning Committee	Dr. Levine provided opening remarks on behalf of the Strategic Planning Committee and noted appreciation for the work of the committee for making progress on strategic planning. Dr. Cook presented an update on the strategic planning process. The public comment period for the proposed National Priorities for Health commenced on June 28th and will end on August 27th. During the 60-day public comment period for the proposed National Priorities, the Strategic Planning Committee (SPC) and the Board will consider the proposed Research Agenda. The Research Agenda will establish the framework through which PCORI achieves progress on the National Priorities, supports the ability to be responsive to stakeholders, and fulfills PCORI's statutory requirements. The Research Agenda will stem from the National Priorities and inform the topic development process that articulates focused areas for funding. The development of the Research Agenda will include opportunities for public and stakeholder input including a specific public comment period on the proposed Research Agenda. Cook also reviewed the overall timeline of the Strategic Planning process. The Board is expected to begin discussions on the proposed Research Agenda in September and is expected to consider the final National Priorities for Health in October. Additionally, work on the Research Agenda and Strategic Plan development will take place through April 2022. The Board is expected to consider the final Strategic Plan for approval in May 2022. The Board commented that the iterative input and revision process represents a unique collaboration between the Board and PCORI staff that could serve as a template for future endeavors.
Wrap-up - Christine Goertz, DC, PhD	Dr. Cook reviewed the Board meeting highlights. Dr. Goertz congratulated all the applicants who were awarded funding and thanked all that joined the call. The meeting ended at 2:01 pm.

Minutes were approved by the PCORI Board of Governors 09-27-2021

ATTACHMENT A:

Cycle 3 2020 Research Award Slates

Phased Large Awards for Comparative Effectiveness Research (PLACER) PFA	Achieving Blood Pressure Goals After Stroke
	Large pragmatic trial to prevent suicide attempts, deaths in moderate-to-high risk youth
	PRECIDENTD (PREvention of Cardiovascular and DiabEtic kidNey disease in Type 2 Diabetes)
	Specialty Compared to Oncology delivered Palliative Care for Patients with Acute Myeloid Leukemia (SCOPE-Leukemia)
	THRIVE: Trajectories of Recovery after Intravenous Propofol vs inhaled Volatile anesthesia

Suicide Prevention: Brief Interventions for Youth Targeted PFA	A Comparison of Two Brief Suicide Prevention Interventions Tailored for Youth on the Autism Spectrum
	Comparative Effectiveness of Two Culturally Centered Suicide Intervention for Alaska Native Youth
	Preventing Suicide among Sexual and Gender Diverse Young Adults in Primary Care in Texas
	Youth Partners in Care for Suicide Prevention (YPIC-SP)

Cycle 3 2020 Broad PFA:

Addressing Disparities	BEhavioral Health Stratified Treatment (BEST) to optimize transition to adulthood for youth with IDD
	Black midwives for Black women: Maternity care to improve trust and attenuate structural racism
	Clinically-integrated Breastfeeding Peer Counseling to Promote Breastfeeding Equity
	Culturally Adapted Online Couples Communication Program for Latina Breast Cancer Patients*
	Evaluation of telehealth services on mental health outcomes for people with IDD
	Reducing Racial Disparities in Maternal Care through Data-Based Accountability and Doula Support
	The Path to Optimal Black Maternal Heart Health: Comparing Two CVD Risk Reduction Interventions
	Vida Sana y Completa Trial: Treating obesity and food insecurity among Latina women*
Improving Health Care Systems	Comparative Effectiveness Trial of Two Supportive Cancer Care Delivery Models for Adults with Cancer*

	Comparing Two Ways to Manage Lymphedema in Head and Neck Cancer Survivors*
	Evaluating the Effectiveness of Mode of Meal Delivery on the Ability of Homebound Older Adults to Remain in the Community
Assessment of Prevention, Diagnosis and Treatment Options	Music Therapy vs. Cognitive-Behavioral Therapy for Cancer-related Anxiety (MELODY)
	Treat-to-Target of Endoscopic Remission in Patients with IBD in Symptomatic Remission: Pragmatic RCT
Improving Methods for Conducting PCOR	Advanced Computation approaches for integrating data to assess effect heterogeneity
	Design and Methodological Development for a Patient Preference SMART*
	Mixed Data Meta Analysis: Integration of Individual Participant and Aggregate Data*
	New methods for planning cluster randomized trials to detect treatment effect heterogeneity
	Semantic Data Quality Standards for Multi-Center Clinical Research Studies and Networks*
	Studying Methods for Ethical and Human Subjects Protections Issues in Digital Health PCOR/CER

ATTACHMENT B:

Dissemination and Implementation Award Slate

Cycle 3 2020 Limited Competition Dissemination and Implementation PFA	Implementing an Intervention to Address Concerns of Older Patients with Cancer Receiving Chemotherapy and Their Caregivers
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