



# Patient-Centered Outcomes Research Institute Board of Governors Meeting

The Wink Hotel  
1143 New Hampshire Ave, NW  
Washington, DC 20036

April 30, 2018

**Board Members Present:**

Grayson Norquist, MD, MSPH, *Chairperson*; Kerry Barnett, JD, *Vice Chairperson*; Larry Becker; Michael Lauer, MD (representing Francis S. Collins, MD, PhD); Allen Douma, MD (via phone); Alicia Fernandez, MD; Christine Goertz, DC, PhD; Leah Hole-Marshall, JD; Russell Howerton, MD, FACS; Gail Hunt; Francis Chesley, Jr. MD (representing Gopal Khanna, MBA); Harlan Krumholz, MD, SM; Barbara McNeil, MD, PhD; Ellen Sigal, PhD; Kathleen Troeger, MPH; Robert Zwolak, MD, PhD

**Board Members Absent:**

Debra Barksdale, PhD, RN; Richard Kuntz, MD, MSc; Sharon Levine, MD; Freda Lewis-Hall, MD

**Methodology Committee Members Present:**

Robin Newhouse, PhD, RN; and Steve Goodman, MD, MHS, PhD (via phone)

**Executive Staff Present:**

Joe Selby, MD, MPH, *Executive Director*; Yen-Pin Chiang, PhD; MPA; Mary Hennessey, Esq.; Michele Orza, ScD; Jean Slutsky, PA, MSPH; MD; Evelyn P. Whitlock, MD, MPH; Regina Yan, MA

AGENDA ITEMS	RELATED MINUTES
<p><b>Welcome and Call to Order</b></p> <p><b>Consider for Approval:</b> Minutes of March 20, 2018 Board Meeting</p> <ul style="list-style-type: none"> <li>– Grayson Norquist, MD, MSPH</li> </ul>	<p>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.</p> <p><i>The following motion was made by Robert Zwolak and seconded by Russell Howerton.</i></p> <p><b>Motion:</b> Approve the Minutes of the March 20, 2018 Board Meeting.</p> <p><i>Approved by a majority vote of the voting Board members (no opposed, no abstentions); Allen Douma was not present for this vote.</i></p>
<p><b>Executive Director’s Report</b></p> <ul style="list-style-type: none"> <li>– Joe Selby, MD, MPH</li> </ul>	<p>Dr. Selby announced the Government Accountability Office (GAO) released its 8-year report on the activities funded by the Patient-Centered Outcomes Research Trust Fund. GAO concluded that PCORI committed funds primarily to research and data capacity efforts; and awards for dissemination and implementation of findings were limited as most research was still underway. GAO also interviewed PCORI officials responsible for planning and carrying out comparative effectiveness research (CER) activities and interviewed officials from stakeholder organizations representing potential users of CER, including public and private payer organizations, provider organizations and patient organizations. He noted that the report is a straightforward description of PCORI activities with no criticisms or recommendations for improvement.</p> <p>Dr. Selby gave an update on the efforts being conducted to advance PCORI’s strategic plan. He noted establishment of a horizon scanning program was underway to help identify and monitor target technologies and therapeutics in healthcare. The anticipated program aims to identify important new therapeutics and technologies before they enter the market and help PCORI identify key research questions as technologies enter the market. The horizon scanning program is envisioned to be linked with other activities PCORI is undertaking, such as evidence mapping and topic brief summaries to compliment the information provided in each of the singular products.</p> <p>Board members commented that it would be important to proceed deliberately due to the amount of information currently available. Members recommended PCORI play a role in generating evidence and information for patients, noting information currently available has varying degrees of validation. PCORI’s work in horizon scanning could help mitigate uncertainty around what current information is trustworthy, actionable, and validated.</p> <p>Dr. Selby announced an upcoming series of analyses conducted by PCORI that will compare PCORI’s and the National Institutes of Health’s comparative effectiveness research portfolio. Selby described the first analysis, a comparison of portfolio characteristics, and stated it would inform the work conducted on the subsequent analyses.</p>

	<p>Board members noted the potential usefulness of the information and requested the Methodology Standards be reviewed for possible inclusion during the comparison of portfolio characteristics. Board members acknowledged that not all the Methodology Standards could be coded for; however, a select few should be considered.</p> <p>Dr. Selby concluded his Executive Director’s Report with a review of the day’s agenda and joined with other Board members to thank Dr. Evelyn Whitlock, PCORI’s Chief Science Officer, for her contributions to PCORI during her tenure. Dr. Whitlock will be departing from PCORI in June.</p>
<p><b>Consider for Approval:</b> Dissemination and Implementation – a new Implementation PFA concept</p> <ul style="list-style-type: none"> <li>- <i>Larry Becker and Jean Slutsky, PA, MSPH</i></li> </ul>	<p>Larry Becker, a member of the Engagement, Dissemination, and Implementation Committee (EDIC) on behalf of EDIC Chair Debra Barksdale, introduced Jean Slutsky, PCORI’s Chief Engagement and Dissemination Officer, who presented an EDIC-endorsed concept for the development of a new funding announcement for the Dissemination and Implementation (D&amp;I) Program. This proposed new funding initiative, titled, “<i>Implementation of Evidence from Major PCORI Research Investments,</i>” will provide a mechanism for PCORI to fund a larger and broader pool of applicants with larger projects to implement findings from PCORI’s funding of high-priority CER initiatives. These high-priority CER investments, which represent approximately \$800M in PCORI funding, include about 90 studies funded under PCORI Targeted PFAs (tPFAs), Pragmatic Clinical Studies (PCS), PCORnet Demonstration Studies, and broad studies with very strong potential for impact. This proposed funding announcement is anticipated to be released in Cycle 3 2018, will allow for a maximum budget of \$2.5M total costs per project and up to three years project period, and would be authorized for a total of up to \$10M per cycle, with an anticipated 2 cycles per year. Jean Slutsky reviewed the anticipated timeline for the development and release of the PFA, the application review process, and approval of awards.</p> <p><i>The following motion was made by Alicia Fernandez and seconded by Gail Hunt.</i></p> <p><b>Motion:</b> Approve the Development of a PFA for Implementation of Evidence from Major PCORI Research Investments, with funding up to \$10M in total costs per cycle and additional cycles not to exceed the Board-approved budget amounts for the D&amp;I program.</p> <p><i>Approved by a majority vote of the voting Board members (no opposed, no abstentions); Allen Douma was not present for this vote.</i></p>
<p><b>Methodology Committee Update</b> <b>Consider for Adoption of New Methodology Standards</b></p>	<p>Dr. Robin Newhouse, Chair of the Methodology Committee, provided a brief background on the Methodology Committee (MC), its members and PCORI’s Methodology Standards.</p> <p>PCORI’s Methodology Standards are required by PCORI’s authorizing law and represent minimal standards for the design, conduct, and reporting of comparative effectiveness research (CER) and patient-</p>

<p>Methodology Standards</p> <ul style="list-style-type: none"> <li>• Studies of Complex Interventions (5 standards, new category)</li> <li>• Data Management Plans (1 standard, will be included as IR-7 in an existing category)</li> </ul> <p>– <i>Robin Newhouse, PhD, RN</i></p>	<p>centered outcomes research (PCOR). These standards are developed by the MC and proposed to the Board for adoption after an opportunity for the public to comment.</p> <p>Dr. Newhouse explained that the MC undertook a systematic process to draft, revise, and finalize six new Methodology Standards. The Board approved these standards for posting for public comment on October 30, 2017 and the proposed new standards were posted for public comment from October 30 – December 29, 2017. After this public comment period, the MC reviewed the public comments and revised the standards, where appropriate. The MC approved 5 five standards in a new category, and one new standard to be brought to the Board for adoption.</p> <p>The titles of the proposed five new standards in the new Standards for Studies of Complex Interventions (SCI) category are:</p> <ul style="list-style-type: none"> <li>• <b>SCI-1:</b> Fully describe the intervention and comparator and define their core functions</li> <li>• <b>SCI-2:</b> Specify the hypothesized causal pathways and their theoretical basis</li> <li>• <b>SCI-3:</b> Specify how adaptations to the form of the intervention and comparator will be allowed and recorded</li> <li>• <b>SCI-4:</b> Plan and describe a process evaluation</li> <li>• <b>SCI-5:</b> Select patient outcomes informed by the causal pathway</li> </ul> <p>The title of the proposed new standard to the Data Integrity &amp; Rigorous Analyses (IR-7) category is:</p> <ul style="list-style-type: none"> <li>• <b>IR-7:</b> In the study protocol, specify a data management plan that addresses, at a minimum, the following elements: collecting data, organizing data, handling data, describing data, preserving data, and sharing data</li> </ul> <p>When asked about potential applicant burden with respect to the new IR-7 standard, while noting also that researchers may not think about data sharing plans in advance, Dr. Newhouse stated that the new standard, along with the existing Methodology Standards, represent minimal standards for research. Dr. Steven Goodman, Vice Chair of Methodology Committee, noted that these requirements can be handled expeditiously in the study protocol and that the Methodology Standards are intended to ensure that researchers are following best practices. Dr. Joe Selby stated that PCORI’s data sharing policy is expected to be brought to the Board in the upcoming months.</p> <p><i>The following motion was made by Christine Goertz and seconded by Ellen Sigal:</i></p> <p><b>Motion:</b> Adopt six new PCORI Methodology Standards:</p> <ul style="list-style-type: none"> <li>• <i>Standards for Data Integrity &amp; Rigorous Analyses</i> <ul style="list-style-type: none"> <li>○ <b>IR-7:</b> In the study protocol, specify a data management plan that addresses, at a minimum,</li> </ul> </li> </ul>
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	<p>the following elements: collecting data, organizing data, handling data, describing data, preserving data, and sharing data.</p> <ul style="list-style-type: none"> <li>• <i>Standards for Studies of Complex Interventions</i> <ul style="list-style-type: none"> <li>○ <b>SCI-1:</b> Fully describe the intervention and comparator and define their core functions.</li> <li>○ <b>SCI-2:</b> Specify the hypothesized causal pathways and their theoretical basis</li> <li>○ <b>SCI-3:</b> Specify how adaptations to the form of the intervention and comparator will be allowed and recorded.</li> <li>○ <b>SCI-4:</b> Plan and describe a process evaluation.</li> <li>○ <b>SCI-5:</b> Select patient outcomes informed by the causal pathway.</li> </ul> </li> </ul> <p><i>Approved by a majority vote of the voting Board members (no opposed, no abstentions and no recusals), Allen Douma and Alicia Fernandez were not present during this vote.</i></p>
<p><b>Stakeholder Panel: Two patient organizations</b></p> <ul style="list-style-type: none"> <li>• National Multiple Sclerosis Society (NMSS)</li> <li>• Michael J Fox Foundation (MJFF)</li> </ul> <p>- <i>Moderated by Gail Hunt</i></p>	<p>The Board heard remarks from a stakeholder panel featuring representatives of patient/consumer/condition research organizations—Bari Talente, Executive Vice President, Advocacy, National Multiple Sclerosis Society (NMSS), and Sohini Chowdhury, Deputy CEO, The Michael J. Fox Foundation for Parkinson’s Research (MJFF). This was the fifth such panel to join an in-person Board meeting, following previous stakeholder panels representing patient/consumer organizations, payers, specialty physicians, and purchasers.</p> <p>Ms. Talente discussed NMSS’ views on how PCORI’s processes worked for the Society, areas where improvements may be found, and other perspectives from NMSS and other colleagues within the patient/condition community.</p> <p>Ms. Chowdhury discussed the MJFF’s approval for, and decision to decline, a Phase II PPRN award. She followed her remarks on this experience with views on their experience as a PCORI applicant, how PCORI may better work with non-traditional or non-academic research organizations, and other areas for further and future engagement with this community.</p> <p>The Board followed their remarks with conversation with the panelists around processes by which this stakeholder community may pursue research funding or have PCORI offer focus on their research priorities. Panelists noted they appreciate PCORI’s focus and work on patient-centered research and activities, but some have expressed frustration in not being successful in obtaining PCORI research funding or having their research priorities taken up by PCORI. Both panelists noted that PCORI has changed in a positive way the manner in which many research and regulatory organizations embrace patient involvement.</p>

<p><b>Consider for Approval:</b> Proposed Slates Cycle 2 2017</p> <ul style="list-style-type: none"> <li>- Evelyn Whitlock, MD, MPH</li> <li>• Pragmatic Clinical Studies</li> </ul>	<p>Dr. Whitlock began her presentation by introducing the proposed slate of awards for the Cycle 2 2017 Pragmatic Clinical Studies (PCS) PFA and reminding the Board of the Merit Review criteria.</p> <p>Of the 54 Letters of Intent (LOIs) submitted, 25 (46%) were invited to submit a full application. Of these, 16 (64% of invited LOIs) applications were submitted. The Selection Committee recommended to fund a slate of 5 applications for a proposed total commitment of \$51M out of the budgeted \$52M.</p> <p>The slate includes five projects:</p> <ol style="list-style-type: none"> <li>1. A Pragmatic Family Centered Approach to Childhood Obesity Treatment</li> <li>2. Comparison of Two- versus Three-Antibiotic Therapy for Pulmonary Mycobacterium Avium Complex Disease</li> <li>3. Integrated Physical and Mental Health Self-Management Compared to Chronic Disease Self-Management</li> <li>4. Multi-Level Interventions for Increasing Tobacco Cessation at FQHCs</li> <li>5. KIDS FACE FEARS: Face-to-Face versus Computer-Enhanced Formats Pragmatic Study of Anxiety</li> </ol> <p>The first project is a two-arm randomized controlled trial (RCT) that aims to study the comparative effectiveness of two clinical treatment options – the staged approach versus the more, initially intensive, family-centered approach, at reducing weight among underserved children and their parents within the primary care setting. The total project cost is \$13.9M.</p> <p>The second project is a multi-site RCT that aims to compare the effectiveness of a macrolide based multi-drug regimen, containing two versus three antibiotics for pulmonary mycobacterium avium complex (MAC), for adult males and females with culture positive non-cavitary pulmonary MAC disease and no prior treatment for pulmonary MAC disease. The total project cost is \$6.2M.</p> <p>The third project is a mixed-methods randomized clinical trial (RCT) that aims to study the comparative effectiveness of Integrated-Illness Management Recovery (I-IMR) versus Chronic Disease Self-Management Program (CDSMP) for improving patient self-management and health outcomes among individuals with serious mental illness diagnosis and a poorly-controlled chronic mental condition. The total project cost is \$7.5M.</p> <p>The fourth project is a multi-level, three-phase, sequential multiple assignment randomized trial. The project aims to study the impact of pragmatic and scalable interventions, at both clinic and patient levels, that are designed to reduce tobacco use and reduce tobacco-related disparities for current adult cigarette smokers, who speak English or Spanish, and who are present at participating Federally Qualified Health Center clinics. The total project cost is \$9.8M.</p>
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<ul style="list-style-type: none"> <li>• Symptom Management for Patients with Advanced Illness</li> </ul>	<p>The fifth project is a two-arm randomized clinical trial that aims to study the comparative effectiveness of face-to-face cognitive behavioral therapy (CBT) vs online CBT for treating anxiety in children and adolescents in pediatric primary care. The total project cost is \$13.6M.</p> <p>When asked in the fifth project how anxiety will be defined and measured in children, Dr. Whitlock noted that there are criteria for anxiety disorders and that the children would have to meet the criteria for mild-to-moderate anxiety in order to participate in the study. She added that in discussions with stakeholders, anxiety in children was indicated as an understudied and under-addressed area that is causing a significant amount of suffering in children and adolescents.</p> <p>Regarding the second project, when asked about the potential difficulty in recruiting the target sample number of 500 patients because the condition is a rare disease, Dr. Whitlock noted that it is expected that this project will have a planning year and PCORI evaluation to ensure enough participants can be recruited.</p> <p><i>The following motion was made by Barbara McNeil and seconded by Alicia Fernandez:</i></p> <p><b>Motion:</b> Approve funding for the recommended slate of awards from the Cycle 2 2017 Pragmatic Clinical Studies PFA.</p> <p><i>Approved by a majority vote of the voting Board members (no opposed, 1 abstention (Grayson Norquist), and 3 recusals: Larry Becker, Kathleen Troeger, and Robert Zwolak). Michael Lauer had earlier indicated his intent to recuse, but was not present during this vote. Harlan Krumholz also was not present for this vote.</i> *****</p> <p>Dr. Whitlock introduced the proposed slate of awards for the Cycle 2 2017 Symptom Management for Patients with Advanced Illness PFA.</p> <p>The objective of the PFA is to fund studies examining long term outcomes for the comparison of evidence-based pharmacological treatments versus other management strategies for symptoms experienced by patients with advanced illness and a life expectancy of greater than six months.</p> <p>Of the 19 Letters of Intent (LOIs) submitted, 12 (63%) were invited to submit a full application. Of these, 9 (75% of invited LOIs) applications were submitted. The Selection Committee recommended to fund a slate of one application for a proposed total commitment of \$2.6M out of the budgeted \$21M.</p> <p>The slate has one project:</p> <ul style="list-style-type: none"> <li>• Personalized Treatments for Advanced Medical Illness Patients with Depression</li> </ul>
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<ul style="list-style-type: none"> <li>Medication-Assisted Treatment Delivery for Pregnant Women with Substance Use Disorders Involving Prescription Opioids and/or Heroin</li> </ul>	<p>The project is a three-arm single site RCT that aims to study the comparative effectiveness of three treatment strategies for depressive symptoms in patients with advanced heart failure. The total project cost is \$2.6M.</p> <p>In response to an observation that the slate has one project, Dr. Christine Goertz, Chair of the Selection Committee, noted that in the future, PCORI may consider removing the pharmaceutical intervention requirement to attract more applicants. Dr. Whitlock also noted that the strict restriction on estimated participant life expectancy could have been a significant factor limiting the number of applications submitted. Dr. Robert Zwolak, Chair of the Science Oversight Committee, responded that the Science Oversight Committee will be discussing the potential reissuance of this PFA during the in-person meeting on May 1, 2018.</p> <p><i>The following motion was made by Barbara McNeil and seconded by Ellen Sigal:</i></p> <p><b>Motion:</b> Approve funding for the recommended slate of awards from the Cycle 2 2017 Symptom Management for Patients with Advanced Illness PFA.</p> <p><i>Approved by a majority vote of the voting Board members (no opposed, no abstentions and no recusals); Harlan Krumholz and Michael Lauer were not present during this vote.</i></p> <p>*****</p> <p>Dr. Whitlock introduced the proposed slate of awards for the Cycle 2 2017 Medication-Assisted Treatment (MAT) Delivery for Pregnant Women with Substance Use Disorders Involving Prescription Opioids and/or Heroin PFA.</p> <p>The goal of the PFA is to fund large, randomized controlled trials or well-justified observational studies that compare the effectiveness for maternal and neonatal outcomes of different models for comprehensive Opioid Use Disorder (OUD) treatment delivery for pregnant women and post-partum women with different levels of addiction severity.</p> <p>Of the 18 Letters of Intent (LOIs) submitted, 14 (78%) were invited to submit a full application. Of these, 10 (71% of invited LOIs) applications were submitted. The Selection Committee recommended to fund a slate of 2 applications for a proposed total commitment of \$10.2M out of the budgeted \$14M.</p> <p>The slate has two projects:</p> <ul style="list-style-type: none"> <li>Moms in Recovery (MORE): Defining Optimal Care for Pregnant Women and Infants</li> <li>PATHways: Comparative Effectiveness Study of Peripartum Opioid Use Disorder in Rural Kentucky</li> </ul>
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<p>Cycle 1 2017</p> <ul style="list-style-type: none"> <li>Optimized Multidisciplinary Treatment Programs for Nonspecific Chronic Low Back Pain</li> </ul>	<p>The first project proposed a prospective observational mixed-methods design to study the comparative effectiveness of integrated versus referral-based MAT delivery models for pregnant women with OUD and their infants for maternal and infant outcomes. The total project cost is \$5.3M.</p> <p>The second project is a cluster RCT that aims to study the comparative effectiveness of alternative models for comprehensive OUD treatment delivery to rural pregnant women for maternal and neonatal outcomes. The total project cost is \$4.9M.</p> <p>With regard to the second project as to whether the investigators have a plan for managing lost follow-up, Dr. Steve Clauser, Program Director for Science, Healthcare Delivery and Disparities Research, responded that the patients would have established relationships with their providers and that the investigators have conducted similar kinds of studies with success.</p> <p><i>The following motion was made by Larry Becker and seconded by Kerry Barnett:</i></p> <p><b>Motion:</b> Approve funding for the recommended slate of awards from the Cycle 2 2017 Medication-Assisted Treatment Delivery for Pregnant Women with Substance Use Disorders PFA.</p> <p><i>Approved by a majority vote of the voting Board members (no opposed, no abstentions and 1 recusal, Robert Zwolak). Harlan Krumholz, Michael Lauer and Ellen Sigal were not present during this vote.</i></p> <p>*****</p> <p>Dr. Whitlock began her presentation by introducing the proposed slate of awards for the Cycle 1 2017 Optimized Multidisciplinary Treatment Programs for Nonspecific Chronic Low Back Pain PFA.</p> <p>The objective of the PFA is to fund large, randomized controlled trials or well-justified observational studies that compare the effectiveness of optimized, multidisciplinary nonsurgical treatment programs involving combined or sequenced interventions for patients with nonspecific chronic low back pain (LBP).</p> <p>Of the 12 Letters of Intent (LOIs) submitted, 7 (58%) were invited to submit a full application. Of these, 5 (71% of invited LOIs) applications were submitted. The Selection Committee recommended to fund one application for a proposed total commitment of \$9.7M out of the budgeted \$43M.</p> <p>The slate has one project:</p> <ul style="list-style-type: none"> <li>Optimizing Treatment Sequencing for Patients with Chronic, Non-Specific Low Back Pain</li> </ul>
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	<p>The project proposed a SMART RCT study design to study the comparative effectiveness of physical therapy versus cognitive behavioral therapy as initial treatments for patients with chronic low back pain. The total project cost is \$9.7M.</p> <p>When asked whether staff thought that this project would result in an implementation opportunity, Dr. Whitlock responded that this project would address an evidence gap, and evidence about which sequences work better for specific populations would be informative to the field and would add to the understanding of how to differentiate between the different types of people who have different types of back pain.</p> <p>Members of the Board asked for thoughts on how to increase the number of strong applications, especially since this is a research area that is of importance to employers, insurers, and other groups. Dr. Goertz indicated that there could be lessons learned in the way that the NIH wrote and distributed a recent pragmatic CER study announcement which resulted in the funding of a significant number of studies.</p> <p><i>The following motion was made by Robert Zwolak and seconded by Russell Howerton:</i></p> <p><b>Motion:</b> Approve funding for the recommended slate of awards from the Cycle 1 2017 Optimized Multidisciplinary Treatment Programs for Nonspecific Chronic Low Back Pain PFA.</p> <p><i>Approved by a majority vote of the voting Board members (no opposed, no abstentions and no recusals). Michael Lauer and Harlan Krumholz were not present during this vote.</i></p>
<p><b>Consider for Approval:</b> Targeted PFA Development</p> <ul style="list-style-type: none"> <li>• Psychosocial Interventions with Office-Based Opioid Treatment</li> </ul> <p>- Evelyn Whitlock, MD, MPH</p>	<p>Dr. Evelyn Whitlock began this presentation by reminding the Board of the PCORI Topic Prioritization Pathway and introducing the proposed development of the Psychosocial Interventions with Office-Based Opioid Treatment for Opioid Use Disorder Targeted PFA.</p> <p>The total commitment requested for this PFA is up to \$25M in total costs (total direct costs per study of \$4M), with an estimated number of 4-5 studies and a maximum project duration of 4 years.</p> <p>. Dr. Whitlock, when asked whether PCORI staff have conducted a review of existing research in this area to ensure that this funding announcement would not be redundant, noted that PCORI has had ongoing conversations with the National Institutes on Drug Abuse (NIDA) which confirmed that the current research question of importance is centered around medication assisted treatment. Dr. Whitlock added that PCORI would allow large observational studies and that research in this area would not be duplicative.</p> <p>The importance of focusing this research area on under-resourced populations was stressed, and it was indicated that this issue has been discussed by the SOC. It was further stressed that PCORI staff</p>

	<p>should ensure that the funding announcement also focuses on traditional, urban, and underserved populations. Dr. Whitlock added that conversations with stakeholders indicated that the amount and nature of psychosocial supports should be needs-based and that it might be more effective to think about stepped-down care, particularly for more vulnerable populations. It was also recommended that the funding announcement include some reference to the issue of comorbid substance use among those with OUD.</p> <p><i>The following motion was made by Barbara McNeil and seconded by Gail Hunt:</i></p> <p><b>Motion:</b> Approve the development of and release of the Psychosocial Interventions with Office-Based Opioid Treatment (OBOT) for Opioid Use Disorder PFA.</p> <p><i>Approved by a majority vote of the voting Board members (no opposed, no abstentions and no recusals).</i></p>
<p><b>Consider for Approval:</b> Proposed Slate for Cycle 2 2017 Partnerships to Conduct Research within PCORnet (PaCR) PFA</p> <p>- Joe V. Selby, MD, MPH</p>	<p>Dr. Joe Selby introduced the proposed slate of awards for the Cycle 2 2017 Partnerships to Conduct Research within PCORnet (PaCR) PFA.</p> <p>The objective of the PFA is to fund multiple high-quality clinical studies to answer important patient- and stakeholder-prioritized CER questions that remain unanswered due to insufficient or inconclusive evidence. The focus of this PFA is to promote PCORnet sustainability through collaboration and engagement with non-PCORI funders in the conduct of CER and to promote greater completeness of PCORnet data through linkages of PPRN patient-level data with other sources, including the electronic data of Clinical Data Research Networks (CDRNs), health plans, and data collected and aggregated in the form of disease registries.</p> <p>Of the 16 Letters of Intent (LOIs) submitted, 14 (88%) were invited to submit a full application. Of these, 10 (71% of invited LOIs) applications were submitted. The Selection Committee recommended to fund four applications for a proposed total commitment of \$20.8M out of the budgeted \$21M.</p> <p>The slate includes four projects:</p> <ol style="list-style-type: none"> <li>1. Comparative Effectiveness of Pharmacogenomics for Treatment of Depression (CEPIO-D)</li> <li>2. Improving Outcomes in Limited Juvenile Idiopathic Arthritis</li> <li>3. Using PCORnet to Compare Blood Pressure Control Strategies</li> <li>4. Comparative Effectiveness of Biologic or Small Molecule Therapies in Inflammatory Bowel Disease</li> </ol> <p>The first project is a prospective randomized controlled trial that aims to study the comparative effectiveness of combinatorial pharmacogenomic guided treatment to best-practice guideline</p>

	<p>concordant treatment to improve well-being in adults with major depressive disorder. The total project cost is \$4.8M.</p> <p>The second project is a RCT that aims to study whether early initiation of a biologic agent (abatacept) prevents disease extension in limited Juvenile Idiopathic Arthritis (JIA) compared to standard treatment with NSAIDs and articular injections for children ages 2-16 within 5 months of clinical diagnosis of JIA. The total project cost is \$7M.</p> <p>The third project proposed a two trial – clinical trial with a cluster RCT and a device trial with an individual-level RCT – study design. The clinical trial study design proposed to compare two levels of support provided to clinics and institutions for improving population blood pressure control rates. The device trial aims to compare home blood pressure monitoring with standard home blood pressure cuff to monitoring with a Bluetooth® enabled cuff with enhanced reporting of blood pressure levels to patient and to physician. The total project cost is \$6.5M.</p> <p>The fourth project proposed both a prospective cohort and retrospective cohort study design to study two different research questions for Crohn’s Disease and Ulcerative Colitis. The first research question, regarding Crohn’s Disease, focuses on the comparative effectiveness of second-line biologic agents (vedolizumab versus ustekinumab) among patients who are anti-TNF primary or secondary non-responders. The second research question, regarding Ulcerative Colitis, focuses on the effectiveness of a second line biologic agent (vedolizumab) versus small molecule (tofacitinib) among patients who are anti-TNF primary or secondary non-responders. The total project cost is \$2.4M.</p> <p>Addressing whether the external partners have rights to prohibit publishing if the study results are not in their favor, Ms. Mary Hennessey, General Counsel of PCORI, indicated that these projects would be funded under PCORI’s research funding agreement, which requires results to be publicly available as provided in PCORI’s authorizing law and will be subject to the same requirements as other research studies funded by PCORI.</p> <p><i>The following motion was made by Ellen Sigal and seconded by Michael Lauer:</i></p> <p><b>Motion:</b> Approve funding for the recommended slate of awards from the Cycle 2 2017 Partnerships to Conduct Research within PCORnet PFA.</p> <p><i>Approved by a majority vote of the voting Board members (no opposed, no abstentions and 3 recusals, Alicia Fernandez, Christine Goertz and Barbara McNeil).</i></p>
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<p><b>PCORnet Update:</b> ADAPTABLE Update</p>	<p>Dr. Joe Selby introduced the PCORnet updates agenda item by informing the Board that there would be presentations on the ADAPTABLE Demonstration Study, querying capabilities in PCORnet, and potential PCORnet dashboard metrics.</p>
<p>Searchable Tool</p> <ul style="list-style-type: none"> <li>- <i>Keith Marsolo, PhD, Cincinnati Children’s Hospital Medical Center</i></li> </ul>	<p>Dr. Keith Marsolo provided the Board with an overview of current querying capabilities in PCORnet and potential options for moving towards a searchable tool in the future. Dr. Marsolo presented three potential general options for updating PCORnet current querying capabilities in the future. The first option was to create a de-identified sample subset of the Common Data Model (CDM) which would be submitted to a centralized repository, which may result in concerns about the misuse of data, risk of re-identification, costs for de-identification, and costs of a new query tool and centralized database. The second option was to enable querying of the univariate statistics describing the CDM so that they can be used to answer simple questions and provide an overview of the aggregate PCORnet population, which may have lower costs and may mitigate some concerns about re-identification due to data existing as aggregate statistics, although, currently, capability supports queries for a single criteria/variable. The third option would be to take steps to implement more rapid turnaround of simple queries by auto-executing results and returning them without review, which reuses existing infrastructure but is not currently reflected in broadly agreed to PCORnet governance policies and would likely result in additional costs to modify current network architecture.</p>
<ul style="list-style-type: none"> <li>- <i>Adrian Hernandez, MD, MHS, Duke Clinical Research Institute</i></li> </ul>	<p>Dr. Adrian Hernandez presented on ADAPTABLE’s progress and lessons learned. He explained how the recruitment process works and informed the Board that as of April 30<sup>th</sup> the study had randomized 7,682 patients. Challenges faced by the study team included varied clinical and patient engagement across centers and sites. In addition, the team learned several lessons regarding what to continue and what to improve for future studies. For example, Dr. Hernandez encouraged the continuation of the ADAPTORS model and discussed how in the future it would be important to increase the return of value to participants. Several successes included the ADAPTORS and the E-Identification of ~400,000 potential participants.</p>
<p>Dashboard Metrics</p> <ul style="list-style-type: none"> <li>- <i>Joe Selby, MD, MPH</i></li> </ul>	<p>Finally, with regard to the Board’s previous suggestion that regular dashboard reports be provided on PCORnet, Dr. Selby explained that the Coordinating Center has been putting together a list of potential metrics covering topics such as patient metrics, Front Door activity, and query metrics.</p> <p>Following the presentation, discussion took place around the modified target enrollment number for ADAPTABLE. Dr. Hernandez explained that even with 15,000 patients enrolled, the study will still be adequately powered. Board members also noted that there remain many lessons to learn about the ways PCORnet can help in recruitment. Regarding querying options, the Board observed that all three options would cost additional money and that it would be important to weigh which option would fit the needs of researchers</p>

	<p>while also having a high impact for PCORnet. It was noted that further discussion would be needed to answer more detailed questions and decide which option would be the best choice. Finally, the Board discussed the proposed dashboard metrics.</p> <p>Board members expressed an interest in including the number of unique requestors coming to the Front Door as well as including data showing the diversity of the PCORnet population. Dr. Selby noted that the Coordinating Center will put together a preliminary dashboard taking into consideration the Board’s suggestions for useful metrics.</p>
<p><b>Public Comment</b>  – <i>Kristin Carman, MA, PhD</i></p>	<p>No members of the public requested the opportunity to make a public comment. Thus, there were no public comments presented during this time.</p>
<p><b>Wrap-up and Adjourn Meeting of the Board</b>  – <i>Grayson Norquist, MD, MSPH</i></p>	<p>Meeting ended at 5:22 pm</p>

**Minutes were approved by the PCORI Board of Governors 05-22-2018**