

Board of Governors Meeting via Teleconference/Webinar

April 21, 2015

12:00-2:00 p.m. ET



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome and Introductions

Steven Lipstein, MHA

Board of Governors

Joe Selby, MD, MPH

Executive Director



Agenda

Time	Agenda Item
12:00-12:05 p.m.	Call to Order, Roll Call, and Welcome Consider for Approval • Minutes of Mar 24, 2015 Board Meeting • Sunset of Select Governance-related Policies
12:05-12:30 p.m.	Consider for Approval: Slate of Fall 2014 Broad PFA Awards
12:30-12:55 p.m.	Consider for Approval: Slate of Fall 2014 Pragmatic Studies Awards
12:55-1:10 p.m.	Consider for Approval: Proposed Amendments to PCORI Bylaws and Charter Revisions for Select PCORI Committees and Advisory Panels
1:10-1:45 p.m.	Consider for Approval: Appointment of Advisory Panelists
1:45-1:55 p.m.	Consider for Approval: Appointment of Secretary and Treasurer
1:55 p.m.	Wrap up and Adjournment



Consent Agenda Items

Steven Lipstein, MHA

Board of Governors

Joe Selby, MD, MPH

Executive Director



Motion for Consent Agenda Items

- Approve minutes from March 24, 2015 Board meeting
- Approve sunset of the following select Governance-related Policies:
 - Policy on Appointment of the Board
 - Policy on Bylaws
 - Policy on Committees of the Board



Board Vote

Call for a Motion to:

- **Approve** each of the Motions on the Consent Agenda, as reflected

Call for the Motion to Be Seconded:

- **Second** the Motion
 - If further discussion, may propose an **Amendment** to the Motion or an **Alternative Motion**

Voice Vote:

- Vote to **Approve** the **Final** Motion
 - Ask for votes in favor, opposed, and abstentions



Fall 2014 Cycle Award Slates

Christine Goertz, DC, PhD

Chair, Fall 2014 Selection Committee

Bryan Luce, PhD, MBA

Chief Science Officer



Fall 2014

Cycle Overview and Slate Recommendations

Bryan Luce, PhD, MBA
Chief Science Officer

Fall 2014 Broad and Pragmatic Studies

Merit Review Criteria

All Broad and Pragmatic Studies PFAs (except Methods)	Improving Methods for Conducting Patient-Centered Outcomes Research
<i>1. Impact of the condition on the health of individuals and populations*</i> <i>2. Potential for the study to improve healthcare and outcomes*</i> 3. Technical merit 4. Patient-centeredness 5. Patient and stakeholder engagement	<i>1. Impact on the field of PCOR methods*</i> <i>2. Potential for the study to improve PCOR methods*</i> 3. Technical merit 4. Patient-centeredness 5. Patient and stakeholder engagement

*Reflects criteria differences between Methods and other Broad PFAs



Slate Overview—Fall 2014 Broad Cycle

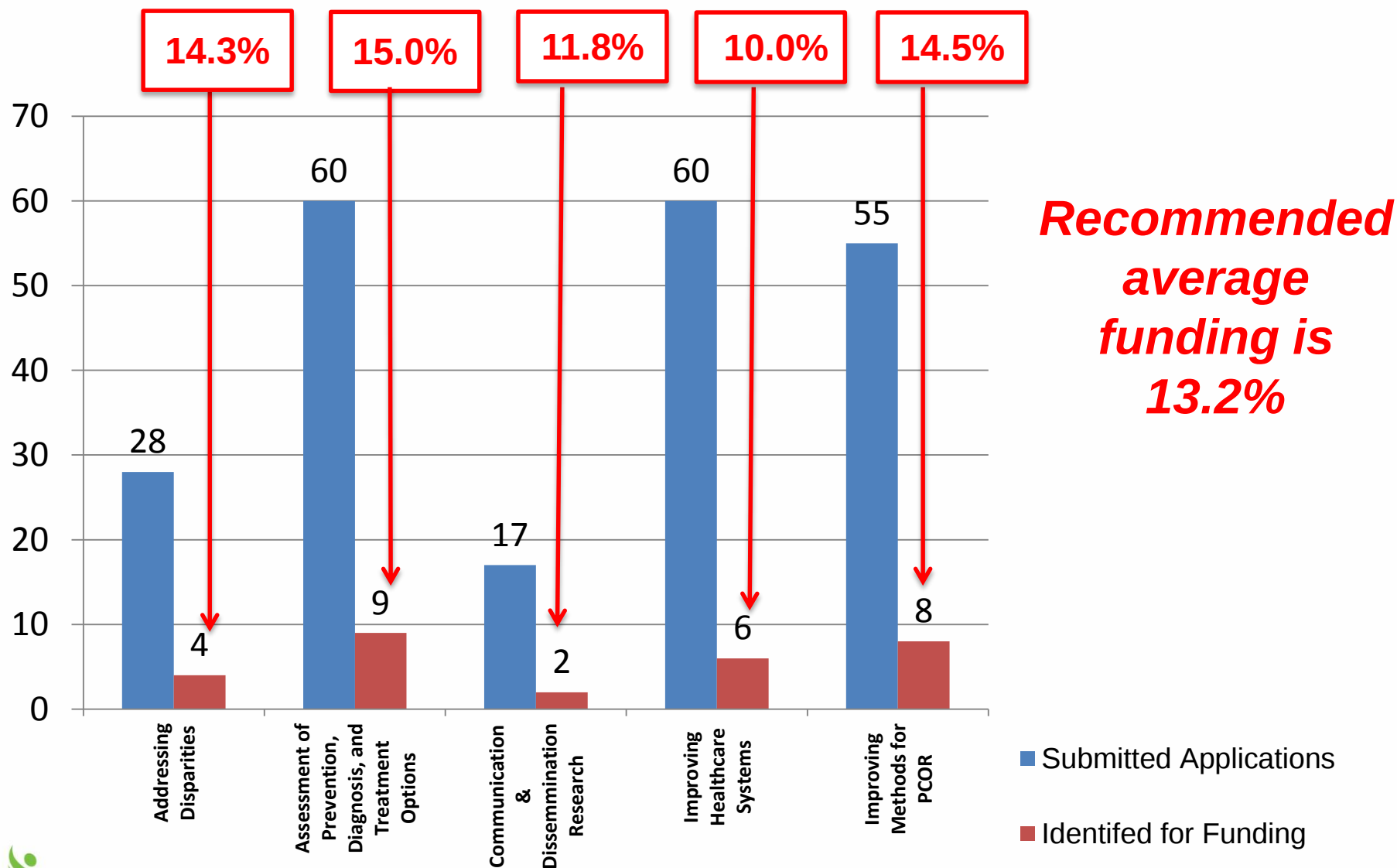
Process Overview

- 833 Letters of Intent (LOIs) submitted
- 290 invited to submit a full application (34.8% of all LOIs)
 - 220 applications submitted (76% of invited)
 - 114 reviewed at the in-person Merit Review
- We are proposing to fund **29 applications** out of 220 (13.2%)
responsive applications



Slate Overview – Fall 2014 Broads

What percentage of applicants are we proposing to fund?



Slate Overview – Fall 2014 Broads

Resubmissions and funding rates

- Of the 833 submitted Letters of Intent (LOIs), 186 were resubmissions (22.3%)
 - Of the 290 LOIs that were invited to submit an application, 84 were resubmissions (29%)
- Of the 220 submitted applications, 58 (26.4%) were resubmissions
- 51.7% applications recommended for funding were resubmissions (compared to 28.3% for the Spring 2014 Broad Cycle)



Conditions

Fall 2014 Broads and Pragmatic Studies Slates

**n=26
Projects**

Each of the proposed projects, excluding Methods, contain one of the listed Disease/Conditions (21 out of the 29 Broads; 5 Pragmatic Studies)

Disease/Condition	Number of Projects (mutually exclusive)
Cancer	3
Cardiovascular Health	3
Kidney Disease	1
Liver Disease	1
Mental/Behavioral Health	4
Multiple/Co-Morbid Chronic Conditions	2
Muscular and Skeletal Disorders	1
Neurological Disorders	2
Nutritional and Metabolic Disorders	1
Rare Diseases	5
Trauma/Injury	3



PCORI Priority Populations

Fall 2014 Broads and Pragmatic Studies Slates

**n=30
Projects**

30 of 34 proposed projects address at least 1 PCORI Priority Population (29 Broads; 5 Pragmatic Studies)

PCORI Priority Population	Number of Projects (not mutually exclusive)
Racial and Ethnic Minorities	16
Low-income	11
Children	10
Women	9
Older Adults	9
Individuals with Multiple Chronic Conditions	8
People Living in Rural Areas	5
Individuals with Disabilities	4
People Living in Urban Areas	4
Low Health Literacy/Numeracy	3
Individuals with Rare Disease	5



Fall 2014 Broad PFA Slate Presentation

Addressing Disparities

*4 Recommended Projects**

Project Title
Pain Coping Skills Training for African Americans with Osteoarthritis
Comparative Effectiveness of a Virtual Reality Platform for Neurorehabilitation of Hemiparesis
Get With The Guidelines® Interventions to Reduce Disparities in Acute Heart Failure Patients Discharged from the Emergency Department (GUIDED HF)
Clinician Language Concordance and Interpreter Use: Impact of a Systems Intervention on Communication and Clinical Outcomes

*Subject to the acceptance of PCORI's contract terms and conditions.
Resubmissions in bold



Assessment of Prevention, Diagnosis, and Treatment Options

*9 Recommended Projects**

Project Title
Treatment Alternatives in Adult Rare Disease; Assessment of Options in Idiopathic Subglottic Stenosis
The Patient-Reported Outcomes Project of Hepatitis C HCV-TARGET (PROP up TARGET)
Intervention and Outcomes in Duarte Galactosemia
Home or Away from Home: Comparing Clinician and Patient/Family-Centered Outcomes Relevant to the Care of Pediatric Acute Myeloid Leukemia during Periods of Neutropenia
Comparative Effectiveness of CARRA Treatment Strategies for Polyarticular Juvenile Idiopathic Arthritis
Comparative Effectiveness Trial to Reduce Child Maltreatment, Improve Client Outcomes and Examine Client Burden
Cancer of the Uterus and Treatment of Stress Urinary Incontinence
Improving Outcomes of Opioid Addicted Prisoners With Extended Release Injectable Naltrexone Before Reentry
Patient-Reported Outcomes for Bladder Management Strategies in Spinal Cord Injury



Communication and Dissemination Research

*2 Recommended Projects**

Project Title
Cardiopulmonary Resuscitation (CPR) Education for Families of Cardiac Patients before Hospital Discharge: Comparing Methods for Real-World Dissemination
Communication to Improve Shared Decision Making in Attention Deficit/Hyperactivity Disorder (ADHD)

*Subject to the acceptance of PCORI's contract terms and conditions.
Resubmission in bold



Improving Healthcare Systems

6 Recommended Projects*

Project Title
Putting Patients at the Center of Kidney Care Transitions
Impact of High Deductible Health Plans on Patients with Bipolar Disorder
Comparative Effectiveness of State Psychotropic Oversight Systems for Children in Foster Care
Integrating Online Weight Management with Primary Care Support: Patient-Centered Strategies for Addressing Overweight and Obesity in Primary Care
Simplifying Survivorship Care Planning: Comparing the Efficacy and Patient Centeredness of Three Care Delivery Models
Does Outpatient Palliative Care Improve Patient-Centered Outcomes in Parkinson's Disease?

*Subject to the acceptance of PCORI's contract terms and conditions.
Resubmissions in bold



Improving Methods for Conducting PCOR

*8 Recommended Projects**

Project Title
Patient-Centered Adaptive Treatment Strategies (PCATS) Using Bayesian Causal Inference
Matching Complex Patients to Treatments: Innovative Statistical Scoring Methods for Treatment Selection
Bayesian Hierarchical Models for the Design and Analysis of Studies to Individualize Healthcare
Developing Bayesian Methods for Noninferiority Trial in Comparative Effectiveness Research
Visual Displays of Qualitative Data to Advance PCOR
Research Ethics in Patient-Centered Outcomes Research
Mapping and Resourcing Patient and Stakeholder Engagement Along 10-step PCOR Continuum Framework
Measuring and Talking to Patients about the Accuracy of Data Used in PCOR

*Subject to the acceptance of PCORI's contract terms and conditions.
Resubmissions in bold



Slate Overview – Fall 2014 Cycle

Broad PFAs

29
New Projects

Broad PFAs	Allotted	Proposed Total Budget*	<i>Difference</i>	Average Project Budget*
Addressing Disparities	\$8,000,000	\$8,186,841	+ \$186,841	\$2,046,710
Assessment of Prevention, Diagnosis, and Treatment Options	\$32,000,000	\$22,910,763	- \$9,089,237	\$2,545,640
Communications and Dissemination	\$8,000,000	\$3,976,643	- \$4,023,357	\$1,988,322
Improving Healthcare Systems	\$16,000,000	\$16,440,255	+ \$ 440,255	\$ 2,740,043
Improving Methods for Conducting PCOR	\$12,000,000	\$10,044,592	- \$1,955,408	\$1,255,574
TOTALS:	\$76,000,000	\$61,559,094	- \$14,440,906	\$2,122,727

*Total budget = direct + indirect costs



Board Vote

Call for Motion to:

- **Approve** funding for the recommended slate of awards from the Fall 2014 Cycle Broad PFAs

Once the Motion Is Seconded:

- Move to **discuss, amend, or take another action** on the selected topic

Roll Call Vote:

- Vote to **Approve** the **Final** Motion
- Ask for votes in favor, opposed, and abstentions



Fall 2014 Pragmatic Studies Cycle Overview and Slate Recommendation

Fall 2014 Pragmatic Studies PFA

- Goal of PFA:
 - Fund pragmatic clinical trials (PCTs), large simple trials (LSTs), or large-scale observational studies that compare two or more alternatives for
 - Addressing prevention, diagnosis, treatment, or management of a disease or symptom
 - Improving healthcare system-level approaches to managing care
 - Eliminating health or healthcare disparities
- Up to \$10M in direct costs and up to 5 years duration
- Funds available up to \$90M total costs



Slate Overview – Fall 2014 Pragmatic Studies

Process Overview

- 169 Letters of Intent (LOIs) submitted and reviewed
 - 21 LOIs invited to submit full application (12.4% of all LOIs)
 - 16 applications submitted (76% of invited) and reviewed at Merit Review
- Convened post-Merit Review methodology consultation panel with the assistance of our Methodology Committee and Clinical Trials Advisory Panel
- We are proposing to fund 5 projects
 - 4 reviewed with the Fall 2014 Pragmatic Studies applications (25% funding rate)
 - 1 reviewed and recommended by the Spring 2014 Selection Committee; deferred for further scope negotiation



Fall 2014 Pragmatic Studies Funding Slate

*5 Recommended Projects**

Project Title
Anti-tumor necrosis factor (TNF) Monotherapy versus Combination Therapy with Low Dose Methotrexate in Pediatric Crohn's Disease (**1, 2, 3)
MOBILITY: Improving Patient-Centered Outcomes Among Overweight and Obese Youth with Bipolar Spectrum Disorders Treated with Second-Generation Antipsychotics (**1, 2, 3)
A Practical Intervention to Improve Patient-Centered Outcomes After Hip Fractures Among Older Adults (Regain Trial) (**1, 2, 3)
Integrating Patient-Centered Exercise Coaching into Primary Care to Reduce Fragility Fracture (**1, 2)
Pragmatic Randomized Trial of Proton vs. Photon Therapy for Patients with Stage II or III Breast Cancer*** (**1, 2)

*Subject to the acceptance of PCORI's contract terms and conditions.

** 1: PCORI Priority; 2: IOM CER 100; 3: AHRQ Future Research Needs—priority areas are not mutual exclusive

***Reviewed during the Spring 2014 Pragmatic Studies Cycle



Project #1

Anti-TNF Monotherapy versus Combination Therapy with Low Dose Methotrexate in Pediatric Crohn's Disease

- Research Question
 - What is the comparative effectiveness of low-dose oral methotrexate in combination with anti-tumor necrosis factor (TNF) biological therapy versus anti-TNF alone in the treating children with Crohn's Disease in terms of induction, maintenance of remission, patient-reported outcomes, and adverse events?
- Study Design/Sample Size/Population
 - Multi-center, double-blind, pragmatic clinical trial of 425 patients; children with Crohn's Disease
- Outcomes
 - Pediatric Crohn's Disease Activity Index, patient-reported outcomes, and mucosal healing
- Total Budget: \$7,909,644



Project #1 (cont.)

Anti-TNF Monotherapy versus Combination Therapy with Low Dose Methotrexate in Pediatric Crohn's Disease

- Engagement
 - Partnered with major patient advocacy group, initiated a parent working group and Patient Advisory Council (PAC), and mounting a patient/parent engagement campaign to increase awareness and participation
- Potential Impact
 - Improve clinical treatment of pediatric Crohn's Disease



Project #2

MOBILITY: Improving Patient-Centered Outcomes Among Overweight and Obese Youth with Bipolar Spectrum Disorders Treated with Second Generation Antipsychotics (SGAs)

- Research Question
 - To assess whether metformin, when added to a healthy lifestyle intervention (LIFE: diet + exercise), is better than LIFE alone for improving weight and metabolic health in overweight and obese youth with bipolar spectrum disorders
- Study Design/Sample Size/Population
 - Multi-site, parallel-group, randomized pragmatic trial in 1,800 patients (8-17 years) who are overweight or obese and receiving SGA treatment at private & public mental health treatment centers in the northeast and mid-west
 - Overweight (body mass index (BMI) > 85th percentile) or obese youth with bipolar spectrum disorders



Project #2 (cont.)

MOBILITY: Improving Patient-Centered Outcomes Among Overweight and Obese Youth with Bipolar Spectrum Disorders Treated with Second Generation Antipsychotics

- Outcomes
 - Primary: change in normalized body mass index (BMI)
 - Secondary: metabolic syndrome and its components, medication adherence, treatment satisfaction, psychiatric outcome measures, quality of life, and functional outcomes of patients and caregivers
- Total Budget: \$12,906,187
- Engagement
 - Involves patient/parent partners, advocacy and professional organization leaders, payers, and other key stakeholders in all study decisions
 - Youth members with bipolar spectrum disorders also participate in the study recruitment/retention and stakeholder engagement committees
- Potential Impact
 - Findings could provide guidance on strategies to alleviate weight gain and metabolic side effects seen with second generation antipsychotics



Project #3

A Practical Intervention to Improve Patient-Centered Outcomes After Hip Fractures Among Older Adults (Regain Trial)

- Research Question
 - What is the comparative effectiveness of spinal versus general anesthesia on health and disability in older adults experiencing hip surgery?
- Study Design/Sample Size/Population
 - RCT, 1600 patients (age 50+) who require surgery for an acute hip fracture
- Outcomes
 - Assessed at 1-day post-surgery: Acute post-operative pain, satisfaction with care, major inpatient morbidity
 - Assessed at 60- and 180- days post-surgery: Ability to walk without assistance (primary), overall health and disability, pain, ability to return home after fracture, and mortality



Project #3 (cont.)

A Practical Intervention to Improve Patient-Centered Outcomes After Hip Fractures Among Older Adults (Regain Trial)

- Total Budget: \$11,878,793
- Engagement
 - 3 national clinical specialty groups, national patient advocacy groups, major payer, and 8 member community patient and caregiver advisory group involvement
- Potential Impact
 - Each year in the US, more than 300,000 patients need surgery to treat hip fractures. Evidence about outcomes related to choice of anesthesia is highly relevant to these patients.



Project #4

Integrating Patient-Centered Exercise Coaching into Primary Care to Reduce Fragility Fracture

- Research Question
 - What is the comparative effectiveness of exercise coaching compared with usual care in reducing fragility fractures and serious fall-related injuries in older adults?
- Study Design/Sample Size/Population
 - RCT of 2,000 patients with a fragility fracture in past 5 years
 - Older adults (age 65+) with history of prior fragility fracture
- Outcomes
 - Primary: Fragility fractures and other serious fall-related injuries (FF/SFRI)
 - Secondary: Muscle strength, bone density, physical function, muscle mass, and depression/loneliness
- Total Budget: \$13,950,066



Project #4 (cont.)

Integrating Patient-Centered Exercise Coaching into Primary Care to Reduce Fragility Fracture

- Engagement
 - Patients: 113 involved in the design pre-submission; 3 patient investigator partners; 4 patient representatives on Advisory Board
 - Stakeholders: major clinician groups, payers, and local agencies on aging
- Potential Impact
 - A minimal resource intensive intervention to prevent the most feared complication of osteoporosis, recurring fragility fractures and serious falls-related injuries



Project #5

Pragmatic Randomized Trial of Proton vs. Photon Therapy for Patients with Stage II or III Breast Cancer

- Research Question
 - Does proton therapy reduce major cardiovascular events related to breast cancer treatment and improve quality of life compared with photon therapy?
- Study Design/Sample Size/Population
 - Randomized controlled pragmatic trial; 1716 stage II/III breast cancer patients
- Outcomes
 - Major cardiovascular events/complications, quality of life, body image and function, cancer control measures, side effects, and other adverse events



Project #5 (cont.)

Pragmatic Randomized Trial of Proton vs. Photon Therapy for Patients with Stage II or III Breast Cancer

- Budget: \$11,830,530
- Engagement
 - Diverse stakeholder representation including payers, patient organizations, industry, clinicians, and specialty societies in radiotherapy; stakeholder advisory committees; major payer is engaged
- Potential Impact
 - Fills important evidence gap on the benefits and harms of proton therapy

*Reviewed during the Spring 2014 Pragmatic Studies Cycle



Slate Overview – Fall 2014 Cycle

Pragmatic Studies PFA

5
New Projects

Pragmatic Studies PFA	Allotted	Proposed Total Budget*	<i>Difference</i>	Average Project Budget*
Large Pragmatic Studies to Evaluate Patient-Centered Outcomes	\$90,000,000	\$58,475,220	- \$31,524,780	\$11,695,044

*Total budget = direct + indirect costs; Includes an application from the Spring 2014 Pragmatic Studies Cycle



Board Vote

Call for Motion to:

- **Approve** funding for the recommended slate of awards from the Fall 2014 Cycle Pragmatic Studies PFA

Once the Motion Is Seconded:

- Move to **discuss, amend, or take another action** on the selected topic

Roll Call Vote:

- Vote to **Approve** the **Final** Motion
- Ask for votes in favor, opposed, and abstentions



Proposed Amendments to PCORI Bylaws and Charter Revisions for Select PCORI Committees and Advisory Panels

Mary Hennessey, Esq.
General Counsel



PCORI Governance Document Revisions

- The Board will consider approving proposed amendments to the PCORI Bylaws and proposed revisions to charters of select PCORI Committees and Advisory Panels
- Collectively, the proposed changes:
 - Implement the Board's prior decision to transfer the responsibilities of the Audit and Conflict of Interest Subcommittee of the Governance Committee to the Governance Committee and to sunset the A/COI Subcommittee
 - Reflect the annual review of charters, consistent with requirements of the charters and good governance practice



Proposed Amendments to PCORI Bylaws

- Implement the transfer of responsibilities of the A/COI Subcommittee to the Governance Committee
- Clarify and improve existing provisions:
 - Reorganize and streamline sections on Committees and recognize the Board's authority to create additional committees and working groups
 - Address staggered terms of Board and Methodology Committee members
 - Reflect modern mechanisms of payment primarily through money transfers, not checks
 - Improve organization of several sections



Governance Committee Proposed Charter Revisions

- Audit and conflict of interest responsibilities are added
- References to the A/COI Subcommittee are removed
- Audit matters will be considered by Board members of the Governance Committee
- Governance Committee may engage appropriate advisors to provide expert guidance and recommendations and to advise on its duties



Methodology Committee Proposed Charter Revisions

- Proposed revisions reflect needed updates since the 2011 approval of the charter
- Language is changed to be consistent with other PCORI committee charters
 - Appointment of Chair, Vice Chair
- Language is added to reflect staggered terms to be consistent with Bylaws
- Quorum requirements are specified
- Charter more accurately reflects how the Committee has advised and will continue to advise the Board of Governors and PCORI on matters related to increasing quantity, quality, and timeliness of research information and speed implementation and use of evidence
- The Committee's responsibility to both develop and update the Methodology Standards is reflected



Research Transformation Committee

Proposed Charter Revisions

- Proposed revisions are to align the term and term limits of the Chair and Vice Chair to be consistent with those of the other strategy committees (Science Oversight Committee and Engagement, Dissemination, and Implementation Committee)
 - Terms for Chair and any Vice Chair will be two years, not one. Chair and Vice Chair can serve up to two 2-year terms



Clinical Trials Advisory Panel and Rare Disease Advisory Panel Proposed Charter Revisions

- Number of members and terms revised for consistency
 - 10 to 15 members
 - Panel members will serve staggered 3-year terms
- Clarifications on subcommittees and ad hoc advisory panels
 - Meetings are closed to the public given that members will have access to confidential information (information about individual trials)
- Charters will remain in effect until termination by PCORI's Board of Governors and will be reviewed yearly
- Minor language and organizational revisions to provide consistency across all Advisory Panel charters



Communication and Dissemination Research Advisory Panel Proposed Charter Revisions

- Based on the Board of Governors' discussion during its January 2015 meeting, it is recommended that the following bullet point be removed from the charter:
 - “Act as ambassadors of PCORI by sharing and using information generated from PCORI-funded projects;”



Board Vote

Call for a Motion to:

- **Approve** the proposed amendments to the PCORI Bylaws

Call for the Motion to Be Seconded:

- **Second** the Motion
 - If further discussion, may propose an **Amendment** to the Motion or an **Alternative Motion**

Roll Call Vote:

- Vote to **Approve** the **Final** Motion
 - Ask for votes in favor, opposed, and abstentions



Board Vote

Call for a Motion to:

- **Approve** each of the Revised Charters for PCORI Governance, Methodology, and Research Transformation Committees and Advisory Panels on Clinical Trials, Rare Disease, and Communication, Dissemination and Research

Call for the Motion to Be Seconded:

- **Second** the Motion
 - If further discussion, may propose an **Amendment** to the Motion or an **Alternative Motion**

Voice Vote:

- Vote to **Approve** the **Final** Motion
 - Ask for votes in favor, opposed, and abstentions



Approving New and Reappointed Advisory Panelists

Jean Slutsky, PA, MSHS

Chief Officer of Engagement and Dissemination

Bryan Luce, PhD, MBA

Chief Science Officer



Meeting Topics and Objectives

Advisory Panels Application and Selection Process Overview

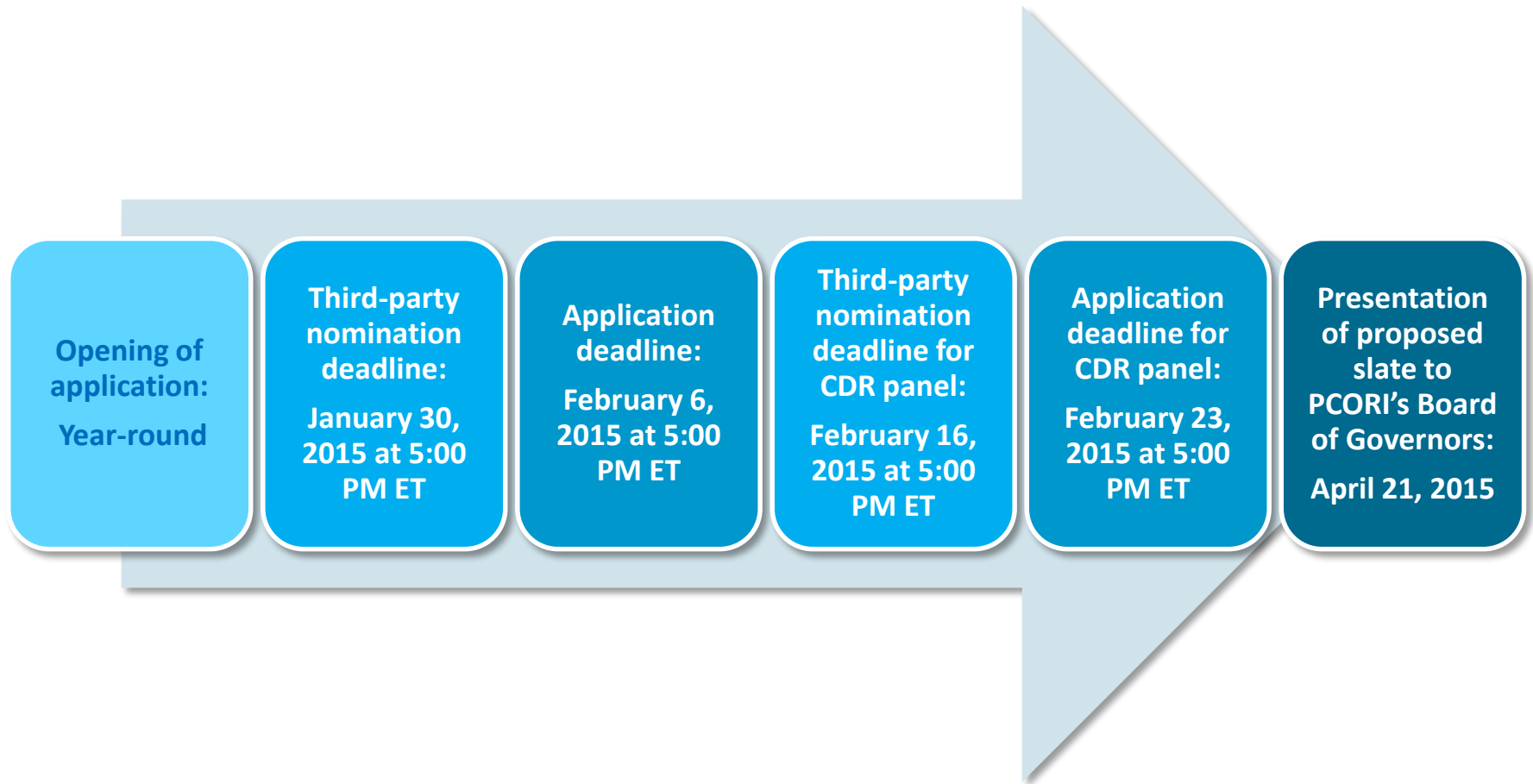
- Key information regarding the openings and applications received in this cycle of selection

Proposed Advisory Panel Members

- Review and approval of the proposed Advisory Panel members



Timeline



Openings and Applications Received

Advisory Panel	Openings	Applications Received
Assessment of Prevention, Diagnosis, and Treatment Options	4	322
Improving Healthcare Systems	6	330
Addressing Disparities	7	247
Patient Engagement	7	288
Communication and Dissemination Research	21	135
Rare Disease	2	112
TOTAL	47	770*

*Applicants were able to apply to multiple Advisory Panels, which is why this number does not equal the sum of the applications received



3rd Party Nominations Received From:

- Academic Consortium for Complimentary and Alternative Healthcare
- Alzheimer's Association
- American Academy of Pediatrics
- American Association on Health and Disability
- American Heart Association
- American Urological Association
- America's Health Insurance Plans
- Association for Community Affiliated Plans
- Association for Frontotemporal Degeneration
- Biotechnology Industry Organization
- Craig Nichols, CTAP Member
- Dialysis Patient Citizens
- Harlan Krumholz, Board of Governors Member
- Infectious Diseases Society of America
- Integrative Healthcare Consortium
- Molina Healthcare
- National Institute of Neurological Disorders and Stroke, National Institutes of Health
- National Kidney Foundation
- National Multiple Sclerosis Society
- NephCure
- North American Spine Society
- Participation Program for Pulmonary Fibrosis; PIMA Medical Institute
- PhRMA
- Robert Wood Johnson Foundation
- Society of Nuclear Medicine and Molecular Imaging
- Stephen Katz, Director, NIAMS
- The Dean's Nursing Policy Coalition
- West Valley Ovarian Cancer Alliance



Advisory Panel Members for Consideration

Advisory Panel	Proposed Number of New Panelists	Proposed Number of Alternate Candidates	Proposed Number of Reappointed Panelists
Assessment of Prevention, Diagnosis, and Treatment Options	4	4	0
Improving Healthcare Systems	6	5	0
Addressing Disparities	7	4	0
Patient Engagement	7	2	0
Communication and Dissemination Research	21	3	N/A
Rare Disease	2	1	13
Clinical Trials	0	0	10
TOTAL	47	19	23

Slate Presentations

- **Communication and Dissemination Research**
- **Patient Engagement**
- **Assessment of Prevention, Diagnosis & Treatment Options**
- **Improving Healthcare Systems**
- **Addressing Disparities**
- **Clinical Trials**
- **Rare Disease**



Communication and Dissemination Research - Overview

Advisory Panel	Proposed Number of New Panelists	Proposed Number of Alternate Candidates	Proposed Number of Reappointed Panelists
Communication and Dissemination Research	21	3	N/A



Communication and Dissemination Research - Proposed Panelists

Name	Stakeholder Group	Brief Bio	Term (in Years)
Frank Rider	Patient/Consumer	Mr. Rider is a Senior Human Services Financing Specialist at the American Institutes for Research, Health & Social Development Program. He has firsthand experience as a patient and his professional skills working with family and children's services, mental health, and habilitation services.	1
Janice Radak	Caregiver/Family Member	Ms. Radak is the Editorial Director of ProEd Communications. She has 30+ years of experience in healthcare communication, received a graduate internship at NCI's Office of Cancer Communication, and was Managing Editor with the American Diabetes Association, among other positions with health related organizations.	1
Danny van Leeuwen	Caregiver/Family Member	Mr. van Leeuwen is a nurse leader, advocate, and patient who has spoken nationally about family caregivers and health information technology. He also hosts a weekly health blog that has more than 2,000 registered users.	1
Kristin Voorhees	Patient/Caregiver Advocacy	Ms. Voorhees is the Director of Healthcare Initiatives for the National Foundation for Celiac Awareness. She has a unique combination as a patient and a health communications professional.	1



Communication and Dissemination Research - Proposed Panelists

Name	Stakeholder Group	Brief Bio	Term (in Years)
Nancy Perrin	Researcher	Dr. Perrin is a Senior Investigator and Senior Director of Research, Data, and Analysis at the Center for Health Research, Kaiser Permanente Northwest. She is a methodologist and biostatistician with expertise in longitudinal and clustered data.	1
Alan Whippy	Clinician	Dr. Whippy is the Medical Director of Quality and Patient Safety for the Permanente Medical Group. She is board certified in Internal and Emergency Medicine, and her work has spanned the spectrum of care from primary prevention to redesigning critical care.	1
Ashish Atreja	Hospital/ Health System	Dr. Atreja is the Director of Sinai AppLab and Chief Technology Innovation and Engagement Officer. He has a dual role of developing innovative apps for patient care, education and research as well as engaging with providers, patients and startups to adopt new technology and improve outcomes.	1



Communication and Dissemination Research - Proposed Panelists

Name	Stakeholder Group	Brief Bio	Term (in Years)
Ruth Parker	Patient/Consumer	Dr. Parker is a Professor of Medicine, Pediatrics, and Public Health at Emory University. She has expertise with cross-disciplinary collaborations, advocacy, and healthy literacy. For over two decades she has partnered with patients to help figure out how we better align health and health care demands, complexities, and information with the skills and abilities of everyone needing to know and understand how to get and use what they need for their health.	2
Helen Osborne	Patient/Caregiver Advocacy	Ms. Osborne serves as the president of Health Literacy Consulting, and is the founder of Health Literacy Month. She also produces and hosts a podcast, speaks about health literacy at conferences worldwide, and serves as a plain language writer/editor on a wide range of topics.	2
Andy Rosenberg	Patient/Caregiver Advocacy	Mr. Rosenberg is the founder of Thorn Run Partners and the Deputy Director of the Partnership to Improve Patient Care. He has 20+ years of experience as a health care and disability policy consultant, in addition to his experience as a caregiver.	2
Neela Goswami	Researcher	Dr. Goswami is an academic physician at Emory University whose research focuses on TB, HIV/AIDS, and STDs, and is centered around increasing access to care to patients in the Southeastern U.S.	2



Communication and Dissemination Research - Proposed Panelists

Name	Stakeholder Group	Brief Bio	Term (in Years)
Sandi Smith	Researcher	Dr. Smith is the Director of Health and Risk Communication Center and professor in the Department of Communication at Michigan State University. Her research centers on the impact of communication on health behavior.	2
Nancy Blake	Clinician	Dr. Blake has been the Nursing Director at Children's Hospital Los Angeles for over 20 years. She is also an active member of the American Association of Critical Care Nurses.	2
Cornell Wright	Policy Maker	Mr. Wright is the Director of the NC Office of Minority Health and Health Disparities. He is an active member of the health community and has served in previous roles at Duke University, University of North Carolina, American Heart Association, and the Center for Health and Healing.	2



Communication and Dissemination Research - Proposed Panelists

Name	Stakeholder Group	Brief Bio	Term (in Years)
LaRita Jacobs	Patient/Consumer	Ms. Jacobs has over 20 years of experience in patient advocacy, for which she has received many awards. She currently serves as a freelance medical and human interest journalist and presents to medical and patient groups.	3
Janice Buelow	Patient/Caregiver Advocacy	Dr. Buelow is the Vice President of Research and Programs at the Epilepsy Foundation of America, and has also served as an Associate Professor and Chair of the Department of Adult Health at Indiana University's School of Nursing.	3
Lauren McCormack	Researcher	Dr. McCormack is the Director of RTI's Center for Communication Science. Her work bridges the fields of communication and dissemination and involves developing and evaluating interventions that promote patient-centered care and informed decision making.	3



Communication and Dissemination Research - Proposed Panelists

Name	Stakeholder Group	Brief Bio	Term (in Years)
Michael Pignone	Researcher	Dr. Pignone is a professor and Chief of the Division of General Internal Medicine at University of North Carolina-Chapel Hill and is the Director of the UNC Institute for Healthcare Quality Improvement. His research is focused on chronic disease prevention and treatment and on improving medical decision making with particular emphasis on the needs of patients with limited literacy and numeracy.	3
Robert Volk	Researcher	Dr. Volk is a professor in the Department of Health Services. He heads the Decision Support Lab at MD Anderson and is on the steering committee for the International Patient Decision Aid Standards (IPDAS) Collaboration.	3
Clifford Ko	Clinician	Dr. Ko is a Professor of Surgery at the UCLA School of Medicine and the Director of Research and Quality at the American College of Surgeons. He is also a double boarded clinical surgeon at a VA hospital.	3
Giovanna Devercelli	Industry	Dr. Devercelli is the Executive Director of Health Economics and Outcomes Research of BI Pharmaceuticals. She has 15+ years of experience in health economics and outcomes research, with particular expertise in clinical trial design and patient-reported outcomes.	3



Communication and Dissemination Research - Alternates

Name	Stakeholder Group	Brief Bio
Tom Kuhn	Patient/Consumer	Mr. Kuhn is a Grant Consultant with Hanover Research. His experience includes project conceptualization and design and evidence-based program design in the fields of health, science, agriculture, higher education, media, and small business.
Rebecca St. Germaine	Patient/Caregiver Advocacy	Ms. St. Germaine is a PhD candidate and a Research/Teaching Assistant in the Pharmaceutical Care Laboratory at the University of Minnesota Twin Cities. She has experience in working with low-income, culturally significant minority populations.
Victoria Stanhope	Researcher	Dr. Stanhope is an Associate Professor at the NYU Silver School of Social Work. Her research agenda has been to understand the ways providers and service users make care decisions and how these processes impact service engagement, implementation, and person-centered outcomes.



Patient Engagement – Overview

Advisory Panel	Proposed Number of New Panelists	Proposed Number of Alternate Candidates	Proposed Number of Reappointed Panelists
Patient Engagement	7	2	0



Patient Engagement – Proposed Panelists

Name	Stakeholder Group	Brief Bio	Term (in Years)
Anjum Khurshid	Researcher	Dr. Anjum Khurshid serves as a Senior Health Systems Strategist at the Louisiana Public Health Institute in New Orleans. He directed the Crescent City Beacon Community program in New Orleans that focused on improving management of diabetes and cardiovascular disease and cardiovascular disease and won the prestigious Healthcare Informatics Innovation Award in 2013..	3
Mark Mishra	Clinician	Dr. Mark V. Mishra is an academic radiation oncologist who also spends a significant amount of time treating cancer patients within a community-based cancer center. He has been working with patients and stakeholder partners within the Baltimore area over the past two years to develop research initiatives at the University of Maryland that will directly answer research questions that are posed by patients.	3
Bennett Levitan*	Industry	Bennett Levitan is a member of MDIC's Patient Centered Benefit-Risk Assessment Steering Committee. He is Senior Director, Epidemiology at Janssen Research and Development, a Johnson & Johnson company. He is a specialist in drug and device benefit-risk assessment.	3

*3rd party nomination



Patient Engagement – Proposed Panelists

Name	Stakeholder Group	Brief Bio	Term (in Years)
Jane Perlmutter	Patient/ Consumer	Jane is an independent consultant who has been involved for the past thirty years as a volunteer in health advocacy. This is as a consequence of her breast cancer diagnosis in 1985 at the age of 36. She is especially interested in clinical trials.	3
Philip Posner	Patient/ Consumer	Philip is a retired faculty member with a 40 year career in medical teaching and research. He now works part time as a science advisor to ORAU. He has had RRMS since 1987 and currently volunteers as an advocate for the National Chapter of the MS Society and serves on their Government Relations Committee. He is also vice chair of WMATA advocating for transportation accessibility.	3
Jimmy Lin	Patient/Caregiver Advocacy Organization	C. Jimmy Lin is a 2012 TED Fellow and Founder & President of Rare Genomics Institute. The Rare Genomics Institute is a non-profit patient advocacy organization that enables patient-centered research for rare diseases and has a network of scientific sites at many academic institutions. RGI helps connect patients with these sites and design experiments that may be helpful to understand their rare diseases. RGI is building patient-centric medical records, a data repository, and even a patient-controlled biobank.	3
Veronica Todaro	Patient/Caregiver Advocacy Organization	Veronica is Vice President, National Programs for the Parkinson's Disease Foundation where she leads strategic initiatives that further patient involvement in research, medical care and support services. She created Parkinson's Advocates in Research (PAIR), a initiative that advances the role of people with Parkinson's in the research.	3



Patient Engagement – Alternates

Name	Stakeholder Group	Brief Bio
Stephen Mikita	Patient/ Consumer	As one of the oldest survivors of Spinal Muscular Atrophy (SMA), a genetic neuro-muscular disease characterized by muscle atrophy and weakness--Mr. Mikita has been uniquely positioned to advocate for the patient perspective at every stage of drug development. Mr. Mikita has been a Utah Assistant Attorney General for 32 years and represents Utah's three largest agencies serving and protecting individuals with disabilities.
S. Trent Rosenbloom	Researcher	Dr. Rosenbloom is a nationally recognized investigator in health information technology evaluation. He also serves as the lead on the Vanderbilt patient portal, which currently reaches 300,000 patients. His research has focused on studying how healthcare providers interact with health information technologies when engaging patients, documenting patient care and making clinical decisions.



Assessment of Prevention, Diagnosis, and Treatment Options - Overview

Advisory Panel	Proposed Number of New Panelists	Proposed Number of Alternate Candidates	Proposed Number of Reappointed Panelists
Assessment of Prevention, Diagnosis, and Treatment Options	4	4	0



Assessment of Prevention, Diagnosis, and Treatment Options - Proposed Panelists

Name	Stakeholder Group	Brief Bio	Term
Leslie Levine	Patient/ Caregiver	Leslie M. Levine is an active health care advocate for the peripheral neuropathy community. She has a rare form of autoimmune neuropathy. Her career prior to becoming ill included medical research and working as a biomedical patent attorney at universities and pharmaceutical companies.	3
Jonathan D. Klein	Researcher	Jonathan D. Klein is Associate Executive Director at the American Academy of Pediatrics with oversight for the Department of Research. As one of the leading child and adolescent health services researchers in the US, Dr. Klein is an expert in research in preventive services and their improvement.	3
Robert Bonomo	Clinician	Robert A. Bonomo is Chief of the Medical Service at the Cleveland VA and is Professor of Medicine, Pharmacology and Molecular Biology and Microbiology at Case Western Reserve University (CWRU) School of Medicine. Dr. Bonomo's major interests are antibiotic resistance, infections in the elderly and the applications of molecular diagnostics to infectious diseases.	3
Michael Herndon	Payer	Mike Herndon earned his medical degree from the Oklahoma State University College of Osteopathic Medicine and is board certified in Family Practice. After 20 years in private practice, he now serves as Sr. Medical Director for the Oklahoma Health Care Authority.	3



Assessment of Prevention, Diagnosis, and Treatment Options - Alternates

Name	Stakeholder Group	Brief Bio
Alice Bast	Patient/Caregiver/Advocacy Organization	Alice S. Bast founded and currently serves as the President & CEO of the National Foundation for Celiac Awareness (NFCA) based on her personal experience with celiac disease. Alice has formed partnerships with major national organizations and has become a leading authority on celiac disease.
Maria Suarez-Almazor	Researcher	Maria E. Suarez-Almazor is the Barnts Family Distinguished Professor at the University of Texas MD Anderson Cancer Center. She is also Deputy Chair for Research in the Department of General Internal Medicine. Her research expertise and interests are in patient-centered outcomes and comparative effectiveness research in patients with chronic diseases.
Ann MacIntyre	Clinician	Ann T. MacIntyre is a physician in private practice, Clinical Associate Professor in the Department of Internal Medicine at Nova Southeastern University, and Director of the Infectious Diseases Fellowship Program at Palmetto General Hospital. Dr. MacIntyre is an active member of the Infectious Diseases Society of America, serving on both the Clinical Affairs Committee and Diagnostics Task Force.
Lawrence Goldberg	Payer	Lawrence Goldberg is Associate Medical Director of OptumHealth Services, where he manages psychiatric and substance use benefits for large corporate employers. Previously, he was Medical Director of the Carrier Clinic, a psychiatric specialty hospital in New Jersey, as well as a clinical faculty member in the Department of Psychiatry of the University of Medicine and Dentistry of New Jersey.



Improving Healthcare Systems - Overview

Advisory Panel	Proposed Number of New Panelists	Proposed Number of Alternate Candidates	Proposed Number of Reappointed Panelists
Improving Healthcare Systems	6	5	0



Improving Healthcare Systems - Proposed Panelists

Name	Stakeholder Group	Brief Bio	Term (in Years)
Lisa Freeman	Patient/ Caregiver	Executive Director of the Connecticut Center for Patient Safety and a faculty member at the Academy for Emerging Patient Safety Leaders. After a catastrophic medical error, she became her husband's caregiver for the remaining 18 years of his life. As an independent Patient Safety Advocate she took courses in patient safety and healthcare quality and represents the patient voice at various conferences, on panels, and several hospital councils.	3
Carolyn Petersen	Patient/ Patient Advocate	Senior editor of Mayo Clinic's health information website. She has been a patient and consumer advocate for 20+ years and served as a PCORI patient stakeholder reviewer, a patient advocate with NCI's cancer Bioinformatics Grid, and a consumer rep for the FDA Center for Devices and Radiological Health advisory panels.	3
Timothy Daaleman	Researcher	Professor and Vice Chair of Family Medicine and Research Fellow in the Program on Aging, Disability, and Long-Term Care in the Cecil G. Sheps Center for Health Services Research at the University of North Carolina at Chapel Hill (UNC). His research background and training is in epidemiology and health services research with substantial experience in conducting mixed-methods research. He is a former NIH Patient-Oriented Career Development awardee (K23) and Robert Wood Johnson Foundation Generalist Faculty Scholar.	3



Improving Healthcare Systems - Proposed Panelists

Name	Stakeholder Group	Brief Bio	Term (in Years)
Bonnie Clipper	Clinician	Chief Nursing Officer at the Medical Center of the Rockies. She is a Robert Wood Johnson Foundation Executive Nurse Fellow and in 2013, was awarded the American Organization of Nurse Executives Nurse Mentor award. She serves on the Editorial Advisory a former NIH Patient-Oriented Career Development awardee (K23) and Robert Wood Johnson Foundation Generalist Faculty Scholar Board for the American Nurses Association newspaper and the ANA Nursing Administration Advisory Panel.	3
Jim Bellows	Hospital/Health System	Senior Director of Evaluation and Analytics in Kaiser Permanente's Care Management Institute where his team produces metrics, program evaluation, and applied research that powers system-wide care delivery improvement initiatives by characterizing opportunities, learning what works, producing data that drives performance, and assessing impact and value.	3
Ravi Govila	Payer	Vice President of Medical Management and PPO at Blue Cross Blue Shield of MI, where he oversees care management programs and network management for the PPO and Medicare Advantage. Previously he served as CMO of Blue Cross Blue Shield of Kansas City, where his responsibilities included population health management, the PCMH and value based provider payment, Pharmacy, Quality/Accreditation and all Care Management programs. Previously, Ravi was system medical director of care coordination and accountable care at BJC Health Care.	3



Improving Healthcare Systems - Proposed Co-Chair

Name	Stakeholder Group	Brief Bio	Term
Proposed New Co-Chair			
Michael Dueñas	Clinician	Chief Public Health Officer of the American Optometric Association where his efforts are aimed at health care reform, legislation, interagency actions, rulemaking and achieving reduced disability and protected health for all people at all life stages. His work experience includes, bench scientific research, private clinical and hospital based practice, teaching, and applied research with service to the US Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion. Dr. Dueñas has served on the National Commission on Vision and Health, George Washington University, School of Public Health and Health Services and testified before the 113th US Congress.	2014 - 2017
Proposed New Chair (Previous Co-Chair)			
Doris Lotz	Payers	Doris Lotz is the Medicaid Medical Director for the State of New Hampshire, where she provides guidance for clinical policy, program development, and strategic planning; oversight to quality improvement, clinical and pharmacy services, and managed care; and actively works to balance clinical and business priorities of the program. She has been an advocate for quality measurement and evidence based improvements in healthcare delivery.	2013 - 2016
Previous Chair			
Trent Haywood	Payers	Trent Haywood is Chief Medical Officer for the Blue Cross and Blue Shield Association, a national federation of 38 independent, community-based and locally operated Blue Cross and Blue Shield companies. As the Association's Chief Medical Officer, he is responsible for the Office of Clinical Affairs, which strives to improve opportunities between providers and BCBS companies to improve the choices of quality healthcare provided to members.	2013 - 2015

Improving Healthcare Systems – Alternates

Name	Stakeholder Group	Brief Bio
Caitlin Morris	Patient/Patient Advocate	Director of the Health System Transformation at Families USA, a national nonprofit, nonpartisan organization dedicated to the achievement of high-quality, affordable health care for all.
Bruce Landon	Researcher	Professor of Health Care Policy and Medicine at Harvard Medical School and a practicing general internist at the Beth Israel Deaconess Medical Center. Dr. Landon has a special interest in the comparative effectiveness of various interventions designed to influence the delivery of health services.



Improving Healthcare Systems – Alternates

Name	Stakeholder Group	Brief Bio
William Borden	Training Institution	Associate Professor of Medicine, Director of Healthcare Delivery Transformation at George Washington University, and practicing cardiologist. Previously, he was on the faculty at Weil-Cornell Medical College in Cardiology and in Healthcare Policy and Research. He also served as Senior Advisor to the Assistant Secretary for Planning and Evaluation in the DHHS Office of Health Policy and recently as Medical Officer in the DHHS's Agency for Healthcare Research and Quality's Center for Outcomes and Evidence.
Arun Patel	Hospital/Health System	Director of Quality, Patient Safety, and Risk Management for the Los Angeles County Department of Health Services, and recently served as the Associate Medical Director at LAC+USC Medical Center. Prior to his current position, Dr. Patel was as a Robert Wood Johnson Foundation, Health Policy Fellow.
Andrea Gelzer	Payer	Senior Vice President and Corporate Chief Medical Officer for AmeriHealth Caritas Family of Companies. She is responsible for medical management strategy, value-based provider partnerships, clinical policy development, quality management, corporate provider network strategy, and medical informatics for all AmeriHealth Caritas health plans and ancillary businesses.



Addressing Disparities - Overview

Advisory Panel	Proposed Number of New Panelists	Proposed Number of Alternate Candidates	Proposed Number of Reappointed Panelists
Addressing Disparities	7	4	0



Addressing Disparities - Proposed Panelists

Name	Stakeholder Group	Brief Bio	Term (in years)
Barbara L. Kornblau	Patient/Consumer	Barbara L. Kornblau is the CEO at the Coalition for Disability Health Equity. As a person with a disability who understands public health, health disparities, and especially disability health disparities policy and research, she has played a significant role in the recognition of disabilities as a disparate population in national health policy.	3
Sinsi Hernandez-Cancio	Patient/Caregiver Advocacy Organization	Sinsi Hernandez-Cancio is the Director of Health Equity at Families USA, where she leads the organization's efforts to advance health equity and reduce health care disparities across all of its issue areas. She has worked in the field of health policy for more than a decade and has a longstanding commitment to advancing social justice and fighting for the rights of people of color, especially vulnerable women and children.	3
Kenneth Mayer	Researcher	Kenneth Mayer, is the Medical Research Director of Fenway Health, a FQHC in downtown Boston, and a Professor at Harvard's Medical School and School of Public Health, and an Attending Physician in Infectious Diseases at Beth Israel Deaconess Medical Center. His research has focused on the development of culturally-tailored HIV treatment and prevention interventions for sexual, gender, racial and ethnic minority patients, and in the conduct of community-based research.	3
Elinor Schoenfeld	Researcher	Elinor Schoenfeld, is a Research Associate Professor of Preventive Medicine and Ophthalmology at Stony Brook University with specialties in Epidemiology, community-based research and engagement, community-based intervention trials, clinical trials and clinical research informatics for large scale epidemiologic studies. As a methodologist and an NIH funded principal investigator, she has an understanding of recruiting for and conducting community based research among diverse populations.	3

Addressing Disparities - Proposed Panelists

Name	Stakeholder Group	Brief Bio	Term (in years)
Cheryl Pegus	Patient/Caregiver Advocacy Organization	Dr. Pegus is a cardiologist and Director of the Division of General Internal Medicine and Clinical Innovation at the NYU School of Medicine, following a 16-year career in the pharmaceutical, insurance and comprehensive disease management industries. She has developed evidence-based programs and technology services, and has studied methods to improve quality of care. Her current research focuses on cardiovascular disease prevention and health disparities.	3
Danielle Pere	Clinician	Danielle Pere is the Associate Executive Director of Programs and Operations at the American College of Preventive Medicine (ACPM) and has 14 years of health care policy experience. At ACPM she is responsible for providing oversight, management, and program development for federal grants, leads ACPM's strategic initiatives around Lifestyle Medicine and health systems transformation, and develops and advances ACPM's business lines.	3
Ronald Copeland	Hospital/Health System	Ronald L. Copeland is Senior Vice President of National Diversity and Inclusion Strategy and Policy and Chief Diversity and Inclusion Officer for Kaiser Permanente. Through multiple collaborations, he leads Kaiser Permanente's program-wide efforts to ensure that its strategic vision for diversity and inclusion is successfully implemented and results in all Kaiser Permanente members receiving care that is high quality, affordable, and equitable.	3



Addressing Disparities - Alternates

Name	Stakeholder Group	Brief Bio
Jodi Hall	Patient/Caregiver	Dr. Jodi Hall is an assistant professor of social work at North Carolina State University and has years of practice experience in low income communities. Her primary research focus is health disparities, particularly among minorities and the elderly. Dr. Hall has been a caregiver for her older sister who died of kidney disease, a brother who died from uncontrolled hypertension and a mother who died from Alzheimer's and cancer.
Katrina Anderson	Patient/Caregiver Advocacy Organization	Katrina L. Anderson currently serves on the Health Ethics Committee for St. John-Providence Health System in Southeast Michigan. Katrina advocates for patient-centered health policy at the state and federal levels through the National Patient Advocate Foundation. Her areas of interest include health communication, ethnic health disparities, cultural competence and patient-provider relationships.
Jennifer Griggs	Researcher	Jennifer J. Griggs is a Professor of Medicine in the Division of Hematology/Oncology in the School of Medicine and of Health Management and Policy in the School of Public Health at the University of Michigan. Her research focuses on disparities in cancer care and on patient-provider communication. She has served as Chair of the Clinical Practice Guidelines Committee of the American Society of Clinical Oncology (ASCO) and is a member of the Health Disparities Committee at ASCO.
Toya Burton	Clinician	Dr. Toya Burton is a staff chiropractor at Whatley Health Services, Inc. She has worked in the field of health disparities for the last 8 years addressing pain. She has also created diabetes, obesity and heart disease education management programs.



Clinical Trials - Overview

Advisory Panel	Proposed Number of New Panelists	Proposed Number of Alternate Candidates	Proposed Number of Reappointed Panelists
Clinical Trials	0	0	10



Clinical Trials - Reappointed Panelists

Name	Stakeholder Group	Primary Affiliation	Brief Bio	Term (in Years)
Sanford Jeames	Patients, Caregivers, and Patient Advocates	N/A	Patient advocate, protocol reviewer and community health educator with extensive experience and knowledge working with minority populations, under-represented and under-served	1
Anne McTiernan	Researchers, Epidemiologists	Fred Hutchinson Cancer Research Center	Researcher with expertise in clinical trials on disease prevention through weight control, physical activity, and chemoprevention	1
Craig Nichols	Researchers, Clinical Trialists	VMMC testicular cancer clinic and SWOG	Cancer clinical trial development researcher with expertise in medical informatics, clinical decision support and Novel Patient and provider engagement	1
Robert Temple	Researchers, Clinical Trialists	Food and Drug Administration	As FDA administrator, advised drug companies on the conduct of their trials and reviewing the results of those trials	1



Clinical Trials – Reappointed Panelists

Name	Stakeholder Group	Brief Bio	Term (in Years)
Margo Michaels	Patients, Caregivers, and Patient Advocates	The Founder of the Education Network to Advance Cancer Clinical Trials (ENACCT) and a national expert in community-based education efforts around cancer clinical research	2
Frank Rockhold	Researchers, Clinical Trialists	Leader of global organizations in research and development. Including clinical trial design, data standards, benefit to risk, clinical research, epidemiology, and most recently pharmacovigilance	2
John Lantos (co-chair)	Researchers, Experts in Ethical Dimensions of Clinical Trials	Pediatrician, bioethicist, and leader in academic medicine.	2
Jason Connor	Researchers, Biostatisticians	Leading expert of Bayesian and adaptive trial design	3
Elizabeth Stuart (chair)	Researchers, Biostatisticians	Academic statistician with expertise in randomized trials, including handling complexities such as missing data, clustering, mediation analysis, and noncompliance	3
Merrick Zwarenstein	Researchers, Experts in Scientific and Health Services	Health services physician and PI with a particular interest in development and evaluation of large scale health service interventions in the real world using mixed methods and including pragmatic randomized trials.	3

Rare Disease - Overview

Advisory Panel	Proposed Number of New Panelists	Proposed Number of Alternate Candidates	Proposed Number of Reappointed Panelists
Rare Disease	2	1	13



Rare Disease - Reappointed Panelists

Name	Stakeholder Group	Brief Bio	Term (in Years)
Jacqueline Alikhaani	Patients, Caregivers, and Patient Advocates	Heart patient and survivor of a rare congenital heart disease misdiagnosed for 48 years.	1
Mardi Gomberg-Maitland*	Clinicians	Expert clinician and researcher in the field of pulmonary vascular disease with a focus on pulmonary arterial hypertension (PAH).	1
Philip Ruff	Industry	Industry background in the rare disease drug pipeline.	1
Russell Teegarden	Patients, Caregivers, and Patient Advocates	Senior healthcare practitioner, executive, and educator with a broad base of experience from positions in clinical pharmacy practice, clinical research, university teaching, medical communication and publishing, pharmacy benefit management, nonprofit patient advocacy, and executive leadership.	1



Rare Disease - Reappointed Panelists

Name	Stakeholder Group	Brief Bio	Term (in Years)
Marilyn Bull*	Clinicians	Pediatric expert in related child health and rare diseases.	2
Kate Lorig	Patients, Caregivers, and Patient Advocates	Born with Gaucher disease and cancer survivor.	2
Marc Skinner	Patients, Caregivers, and Patient Advocates	Hemophilia patient and active national and international patient advocate.	2
Sindy Escobar Alvarez	Researchers	Clinical research expertise in sickle cell disease.	2
Uday Deshmukh	Payers	Payer perspective with additional international health experience, public health training and many years of health policy experience.	2



Rare Disease – Reappointed Panelists

Name	Stakeholder Group	Brief Bio	Term (in Years)
Vincent Del Gaizo (co-chair)	Patients, Caregivers, and Patient Advocates	Father of a systematic onset juvenile idiopathic arthritis patient who is actively involved in the field of pediatric rheumatology research for the past 12 years.	3
Marshall Summar (chair)	Clinicians	Geneticist and pediatrician with expertise in rare diseases.	3
Yaffa Rubenstein	Researchers	Researcher and director at the Office for Rare Diseases Research including directing the Global Rare Disease Patient Registry and Data Repository (GRDR) program.	3
James Wu	Industry	Industry background in academic/clinical medicine and expertise in market access, contracting, and health economics and orphan drug development.	3



Rare Disease – Proposed and Alternate Panelists

Name	Stakeholder Group	Brief Bio	Term (in Years)
Patricia Furlong	Patients, Caregivers, and Patient Advocates	Founding President and CEO of Parent Project Muscular Dystrophy (PPMD), the largest nonprofit organization in the United States solely focused on Duchenne muscular dystrophy (Duchenne). She lost her two sons to the disease and continues to fight it in their honor. She is also on the Board of the National Organization for Rare Disorders (NORD).	3
Lisa Heral	Patients, Caregivers, and Patient Advocates	Registered Nurse with clinical research coordination and project management training and experience, who is a caregiver of a son with a rare disease. Currently serves as a member of the Board of Directors of the Fibrous Dysplasia Foundation (Advocacy Organization for a Rare Orthopedic Disorder). Also on the steering committee for the NIH-Office of Rare Diseases-Global Rare Diseases Repository.	3
Alternate			
Teresa Barnes	Patients, Caregivers, and Patient Advocates	Vice President for the Coalition for Pulmonary Fibrosis (CPF), an organization she helped found in 2001. Having lost 5 family members to a rare lung disease, her experience has fueled her personal and professional efforts to raise awareness and find a cure for deadly rare diseases.	



Board Vote

Call for a Motion to:

- **Approve** the proposed slates of members and terms for all Advisory Panels

Call for the Motion to Be Seconded:

- **Second** the Motion
 - If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion

Voice Vote:

- Vote to **Approve** the **Final** Motion
- Ask for votes in favor, opposed, and abstentions



Appointment of Secretary and Treasurer

Allan Douma, MD

Governance Committee

Mary Hennessey, Esq.

General Counsel



Governance Committee: Review of Treasurer and Secretary Positions

- PCORI's Bylaws provide that the Board will appoint a PCORI Treasurer and Secretary, nominated by the Governance Committee
- In PCORI's early years, the Board appointed the Chairperson of the Board ex officio to serve as Treasurer and the Vice-Chairperson of the Board ex officio to serve as Secretary
- Given the evolution of PCORI's governance structure and executive staff, the Governance Committee recently evaluated various options and discussed recommendations for the future



Governance Committee: Review of Options for PCORI Secretary and Treasurer Positions

Considered Options

- Continue the current approach
- Appoint other Board members to serve as the Treasurer and/or Secretary
 - Finance and Administration Committee Chair to serve as Treasurer, ex officio
 - Governance Committee Chair to serve as Secretary, ex officio
- Appoint Executive Staff member(s) to fill one or both positions
 - Chief Operating Officer to serve as Treasurer, ex officio
 - General Counsel to serve as Secretary, ex officio



Governance Committee: Review of Options for PCORI Secretary and Treasurer Positions

Considered Options

- Continue the current approach
- Appoint other Board members to serve as the Treasurer and/or Secretary
 - Finance and Administration Committee Chair to serve as Treasurer, ex officio
 - Governance Committee Chair to serve as Secretary, ex officio
- Appoint Executive Staff member(s) to fill one or both positions
 - Chief Operating Officer to serve as Treasurer, ex officio
 - General Counsel to serve as Secretary, ex officio



Board Vote

Call for a Motion to:

- **Approve** the appointment of:
 - The Chief Operating Officer to serve, ex officio, as the PCORI Treasurer
 - The General Counsel to serve, ex officio, as the PCORI Secretary

Call for the Motion to Be Seconded:

- **Second** the Motion
 - If further discussion, may propose an **Amendment** to the Motion or an **Alternative Motion**

Voice Vote:

- Vote to **Approve** the **Final** Motion
 - Ask for votes in favor, opposed, and abstentions



Wrap Up and Adjournment

Steven Lipstein, MHA

Board of Governors

