

# Board of Governors Meeting

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Via Teleconference/Webinar

April 16, 2019

12:00 PM – 1:30 PM ET

# Welcome and Introductions

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Grayson Norquist, MD, MSPH

Chairperson, Board of Governors

Joe Selby, MD, MPH

Executive Director

# Agenda



**12:00 PM**

**Call to Order, Roll Call, and Welcome**

**12:00 – 12:05**

**Consider for Approval:** Minutes of the March 19, 2019 Board Meeting

**12:05 – 12:15**

**Consider for Approval:** Proposed Revised Charters for PCORI Committees and Advisory Panels

**12:15 – 1:15**

**Consider for Approval:** Proposed Cycle 2 2018 Slates of Awards

**1:15 PM**

**Wrap Up and Adjournment**

## Call for a Motion to:

- **Approve** the Minutes of the March 19, 2019 Board Meeting

## 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

# Proposed Revised Charters for PCORI Committees and Advisory Panels

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**Christine Goertz, DC, PhD**

Chair, Governance Committee

**Mary Hennessey, Esq.**

PCORI General Counsel



# Update of PCORI Governing Documents

- Charters for PCORI's Committees and Advisory Panels call for an annual or periodic review to be conducted. Changes to most Committee and Advisory Panel charters require Board approval
- Each year, Committees review their respective charter and the charters of Advisory Panel(s) whose activities are overseen by the Committee(s)
- The Governance Committee reviews Committee charters to address overall governance matters, including review for governance consistency and alignment with D.C. nonprofit law
- This year's proposed revisions are primarily governance-related revisions recommended by the Governance Committee

# Update of PCORI Governing Documents



- As a result of the Committee reviews and proposed amendments, the Board is asked to consider approving the following amended PCORI governance documents:
  - Charters for the following Committees:
    - Strategy Committees (EDIC, RTC, SOC)
    - Selection Committee (SC)
    - Methodology Committee (MC)
    - Finance and Administration Committee (FAC)
    - Governance Committee (Gov Comm)

# Highlights of Proposed Revisions to Committee Charters



- **EDIC, RTC, SOC, SC, MC, FAC and Governance Committee charters:**
  - Reflects language recommended by the Governance Committee and the respective Committees to address voting by written consent. This language is consistent with DC nonprofit law and memorializes the way PCORI has historically managed voting by written consent
- **FAC charter:**
  - Reorganizes responsibilities to group similar responsibilities together
  - Reflects language relating to the oversight of PCORI's Board & Methodology Committee Compensation and Reimbursement Policy
- **Governance Committee charter:**
  - Clarifies that advice to GAO regarding appointments relates to the appointment process
- **Selection Committee charter:**
  - Addresses executive sessions and meeting minutes, consistent with other charters
- **Methodology Committee charter:**
  - Reorganizes the order of sections to be consistent with other charters



# Proposed Motion

That the PCORI Board of Governors approve the proposed amended Charters for the following Committees:

- Engagement, Dissemination and Implementation Committee (EDIC)
- Research Transformation Committee (RTC)
- Science Oversight Committee (SOC)
- Selection Committee (SC)
- Methodology Committee (MC)
- Finance and Administration Committee (FAC)
- Governance Committee (Gov Comm)

## Call for a Motion to:

- **Approve** the amended charters of the EDIC, RTC, SOC, Selection Committee, Methodology Committee, FAC and Governance Committee

## 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

# **Broad PFAs**

## Cycle 2 2018 Award Slate

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**Gail Hunt**

Vice-Chair, Selection Committee

**Diane Bild, MD, MPH**

Acting Chief Science Officer

<b>Broad PFAs (excluding Methods)</b>	<b>Improving Methods for Conducting Patient-Centered Outcomes Research</b>
<ol style="list-style-type: none"><li>1. Potential for the study to fill critical gaps in evidence</li><li>2. Potential for the study findings to be adopted into clinical practice and improve delivery of care</li><li>3. Scientific merit (research design, analysis, and outcomes)</li><li>4. Investigator(s) and Environment</li><li>5. Patient-centeredness</li><li>6. Patient and stakeholder engagement</li></ol>	<ol style="list-style-type: none"><li><b>1. Study identifies critical methodological gap(s) in PCOR/CER</b></li><li><b>2. Potential for the study to improve PCOR/CER methods</b></li><li>3. Scientific merit (research design, analysis, and outcomes)</li><li>4. Investigator(s) and Environment</li><li>5. Patient-centeredness</li><li>6. Patient and stakeholder engagement</li></ol>

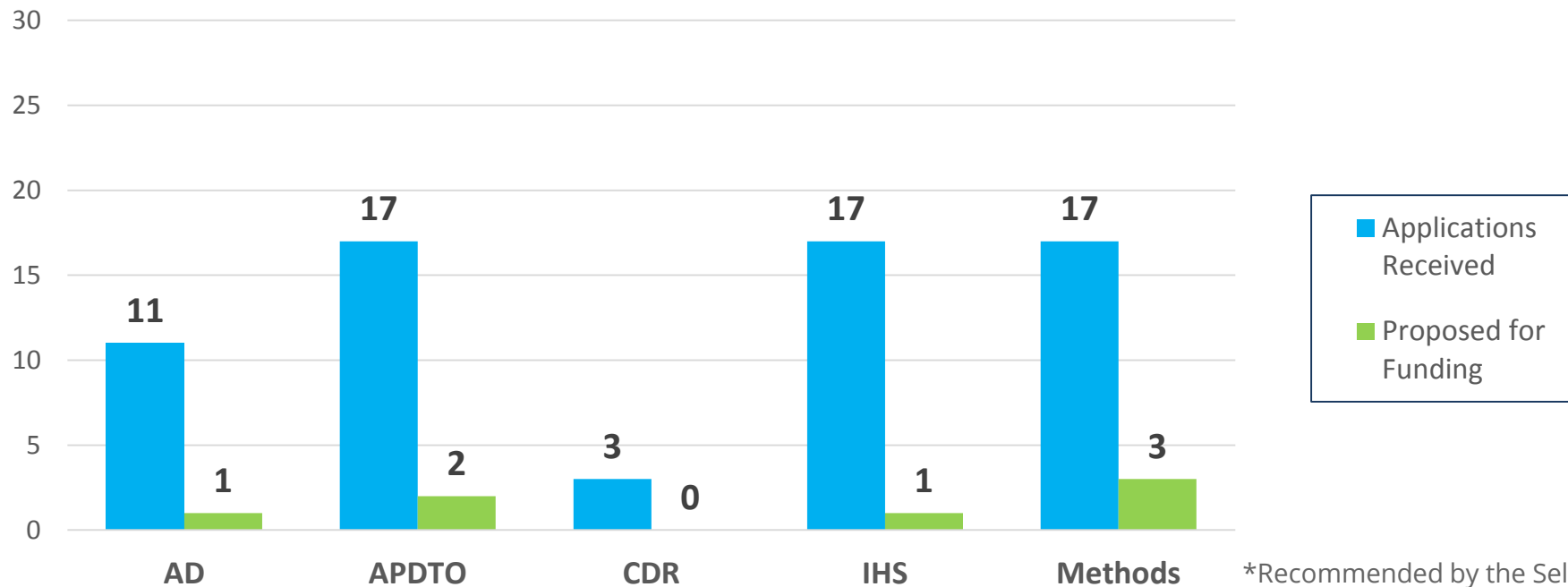
# Cycle 2 2018 – Broad PFAs

## Process Overview



- 182 Letters of Intent (LOIs) received
- 96 LOIs invited to submit a full application
- 65 applications were received
- We are proposing to fund 7 applications\* out of 65 received applications

### Funding rate is 11 percent



\*Recommended by the Selection Committee on March 22 and April 3, 2019 13

# Cycle 2 2018 – Broad PFAs

## Slate Overview



Broad PFA	Amount Posted	Proposed Total Award
Addressing Disparities	\$8M	\$5.6M
Assessment of Prevention, Diagnosis, and Treatment Options	\$32M	\$10.1M
Communication and Dissemination Research	\$8M	--
Improving Healthcare Systems	\$16M	\$2.6M
Improving Methods for Conducting PCOR	\$12M	\$3M
<b>TOTAL:</b>	<b>\$76M</b>	<b>\$21.3M</b>

\* All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract

# Cycle 2 2018 – Addressing Disparities

## Slate of 1 Recommended Project



Project Title
Comparing Approaches to Enhanced Prenatal Care to Improve Maternal and Child Health in Central California

Comparing Approaches to Enhanced Prenatal Care to Improve Maternal and Child Health in Central California

**Resubmissions in Bold**

Note: All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract

# Cycle 2 2018 – Improving Healthcare Systems

## Slate of 1 Recommended Project



### Project Title

Comparative Effectiveness of Direct Admission and Admission through Emergency Departments for Children

#### **Resubmissions in Bold**

Note: All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract



# Cycle 2 2018 – Assessment of Prevention, Diagnosis, and Treatment Options

## Slate of 2 Recommended Projects



### Project Title

**Comparative Effectiveness of Zolpidem and Cognitive Behavioral Therapy for Insomnia in Rural Adults (COZi-R)**

**Cognitive Behavioral Therapy and Real-time-pain-management Intervention for Sickle Cell via Mobile Applications (CaRISMA)**

#### **Resubmissions in Bold**

Note: All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract

# Cycle 2 2018 – Improving Methods for Conducting PCOR

## Slate of 3 Recommended Projects



### Project Title

Comparing “Just-in-Time” to Conventional Consent for Randomized Trials with Usual Care Controls

Validating and Generalizing Personalized Treatment Rules by Leveraging Different Data Sources

Methods for the Design and Conduct of Subgroup Analysis in Observational Studies

#### **Resubmissions in Bold**

Note: All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract

# Cycle 2 2018 – Broad PFAs

## Slate of 7 Recommended Projects\*



<b>PFA</b>	<b>Amount Budgeted</b>	<b>Proposed Total Award</b>
<b>Cycle 2 2018 Broad</b>	<b>\$31M</b>	<b>\$21.3M</b>

\* All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract

## Call for a Motion to:

- **Approve** funding for the recommended award slate from the Cycle 2 2018 Broad PFAs

## 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

# Medication-Assisted Treatment Delivery for Pregnant Women with Substance Use Disorders Involving Prescription Opioids/Heroin

Cycle 2 2018 Award Slate

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**Gail Hunt**

Vice-Chair, Selection Committee

**Diane Bild, MD, MPH**

Acting Chief Science Officer

# Cycle 2 2018 – Targeted PFAs

## Merit Review Criteria



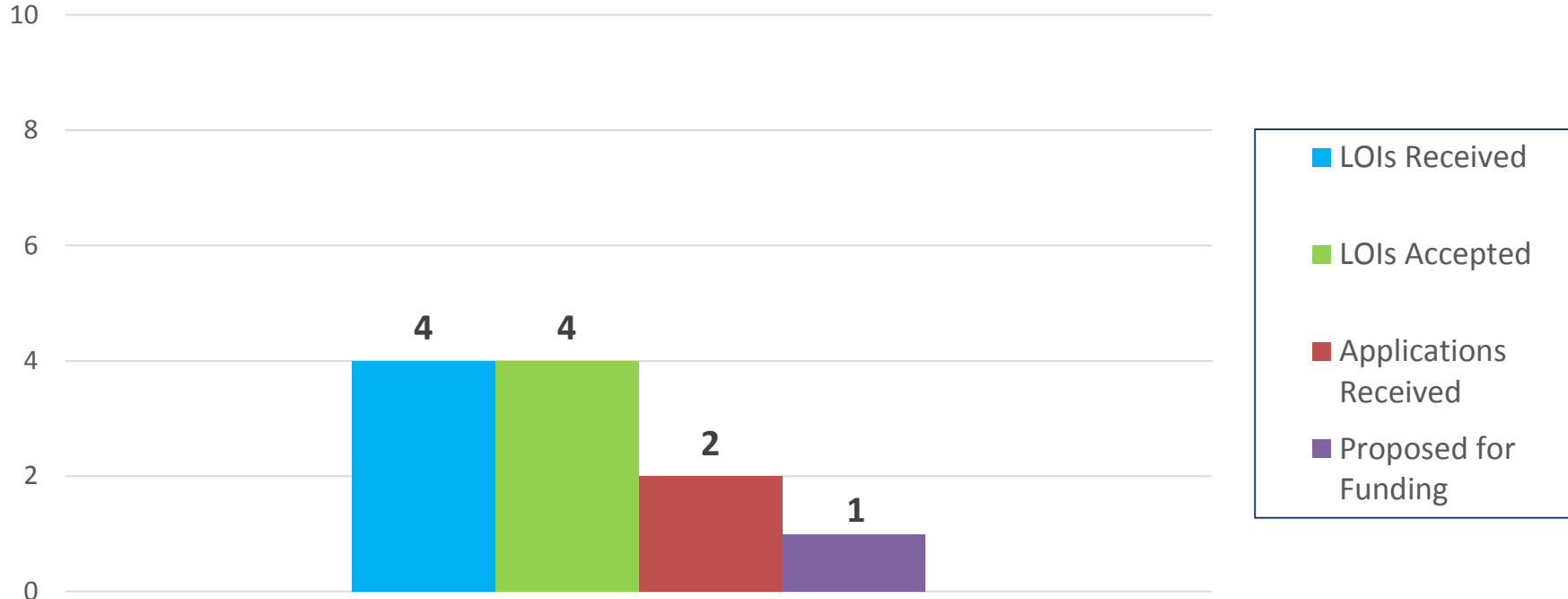
1. Potential for the study to fill critical gaps in evidence
2. Potential for the study findings to be adopted into clinical practice and improve delivery of care
3. Scientific merit (research design, analysis, and outcomes)
4. Investigator(s) and environment
5. Patient-centeredness
6. Patient and stakeholder engagement

# Cycle 2 2018 – Medication-Assisted Treatment for Pregnant Women with Substance Use Disorders Involving Prescription Opioids/Heroin Targeted PFA Process Overview



- 4 Letters of Intent (LOIs) received
- 4 LOIs invited to submit a full application
- 2 applications were received
- We are proposing to fund 1 application\* out of 2 received applications

**Funding rate is 50 percent**



# Cycle 2 2018 – Medication-Assisted Treatment for Pregnant Women with Substance Use Disorders Involving Prescription Opioids/Heroin Targeted PFA

Slate of 1 Recommended Project



Project Title
Support Models for Addiction Related Treatment

**Resubmissions in Bold**

Note: All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract



# Project 1: Support Models for Addiction Related Treatment



- **Research Question:** What is the comparative effectiveness of a collaborative care model vs. a tele-support model for obstetrician-provided office-based opioid treatment (OBOT) to pregnant and postpartum women with opioid use disorder (OUD)?
- **Population:** Pregnant women with OUD
- **Comparator(s):**
  - Collaborative Care
  - Tele-support model
- **Outcomes of Interest:**
  - Primary: Patient treatment initiation, engagement, and retention; patient activation
  - Secondary: Opioid use (other than buprenorphine), perinatal complications, shared decision making, patient-provider relationship, provider burden
- **Potential Impact:** Study findings will enable health systems and providers to select the best model to offer OBOT and could increase the number of primary care and obstetrical providers who can provide medication-assisted treatment (MAT) for pregnant women

# Cycle 2 2018 – Medication-Assisted Treatment for Pregnant Women with Substance Use Disorders Involving Prescription Opioids/Heroin Targeted PFA

Slate of 1 Recommended Project\*



<b>PFA</b>	<b>Amount Budgeted</b>	<b>Proposed Total Award</b>
<b>Cycle 2 2018 Medication-Assisted Treatment Delivery for Pregnant Women with Substance Use Disorders Involving Prescription Opioids/Heroin</b>	<b>\$6M</b>	<b>\$5.6M</b>

\* All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract

## Call for a Motion to:

- **Approve** funding for the recommended award slate from the Cycle 2 2018 Medication-Assisted Treatment Delivery for Pregnant Women with Substance Use Disorders Involving Prescription Opioids and/or Heroin PFA

## 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

# Symptom Management for Patients with Advanced Illness

## Cycle 2 2018 Award Slate

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**Gail Hunt**

Vice-Chair, Selection Committee

**Diane Bild, MD, MPH**

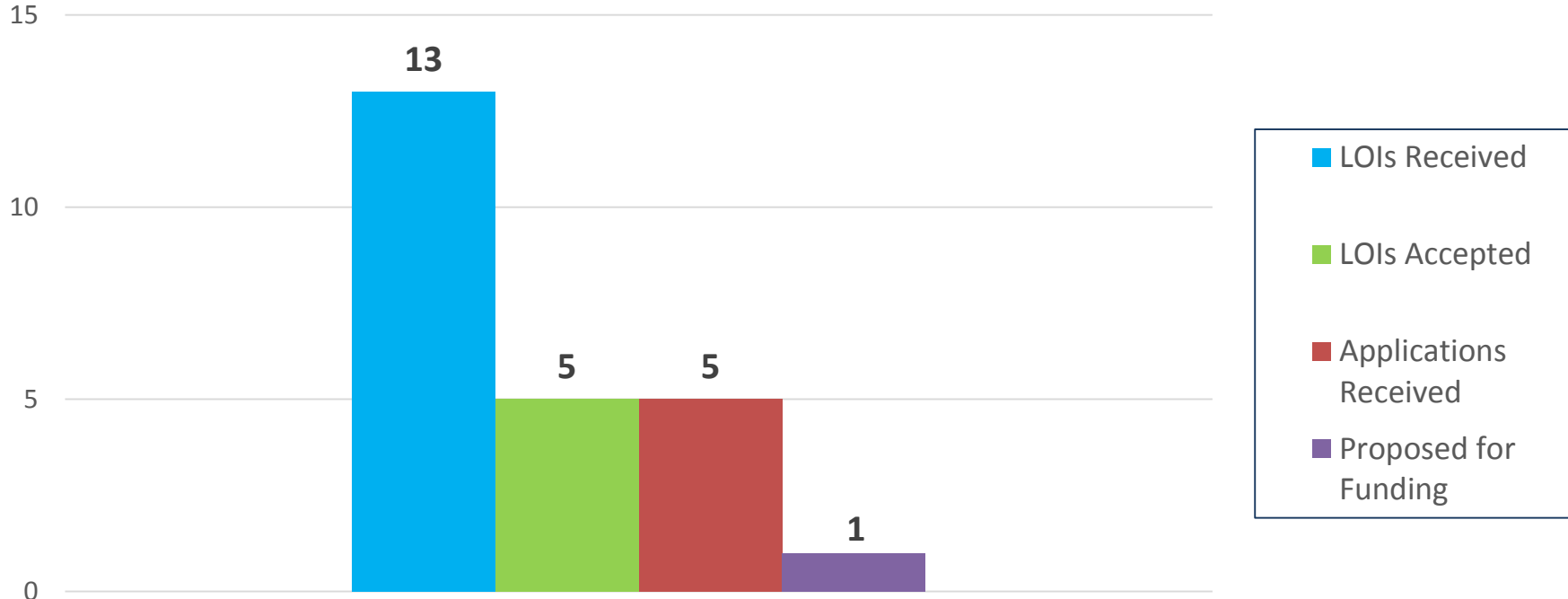
Acting Chief Science Officer

# Cycle 2 2018 – Symptom Management for Patients with Advanced Illness Targeted PFA Process Overview



- 13 Letters of Intent (LOIs) received
- 5 LOIs invited to submit a full application
- 5 applications were received
- We are proposing to fund 1 application\* out of 5 received applications

**Funding rate is 20 percent**



# Cycle 2 2018 – Symptom Management for Patients with Advanced Illness Targeted PFA

## Slate of 1 Recommended Project



Project Title
Integrative Medicine for Pain in Patients with Advanced Cancer Trial (IMPACT)

**Resubmissions in Bold**

Note: All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract

# Project 1: Integrative Medicine for Pain in Patients with Advanced Cancer Trial (IMPACT)



- **Research Question:** What is the comparative effectiveness of acupuncture versus massage therapy for improving pain management and related symptoms among individuals living with advanced cancer?
- **Population:** Adults  $\geq 18$  years of age with a diagnosis of advanced cancer; presence of musculoskeletal pain for at least one month; and moderate to severe pain rating ( $\geq 4$  on a 0-10 rating scale) in the preceding week
- **Comparator(s):**
  - Acupuncture
  - Massage therapy
- **Outcomes of Interest:**
  - Primary: Worst pain severity in past week as measured by Brief Pain Inventory
  - Secondary: Fatigue, sleep disturbance, and quality of life
- **Potential Impact:** The study has the potential to provide evidence on short- and long-term outcomes of two non-pharmacological interventions for pain management and other related symptoms

# Cycle 2 2018 – Symptom Management for Patients with Advanced Illness Targeted PFA

## Slate of 1 Recommended Project\*



<b>PFA</b>	<b>Amount Budgeted</b>	<b>Proposed Total Award</b>
<b>Cycle 2 2018 Symptom Management for Patients with Advanced Illness Targeted PFA</b>	<b>\$15M</b>	<b>\$2.8M</b>

\* All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract



## Call for a Motion to:

- **Approve** funding for the recommended award slate from the Cycle 2 2018 Symptom Management for Patients with Advanced Illness PFA

## 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

# Psychosocial Interventions with Office-Based Opioid Treatment for Opioid Use Disorder

Cycle 2 2018 Award Slate

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Gail Hunt

Vice-Chair, Selection Committee

Diane Bild, MD, MPH

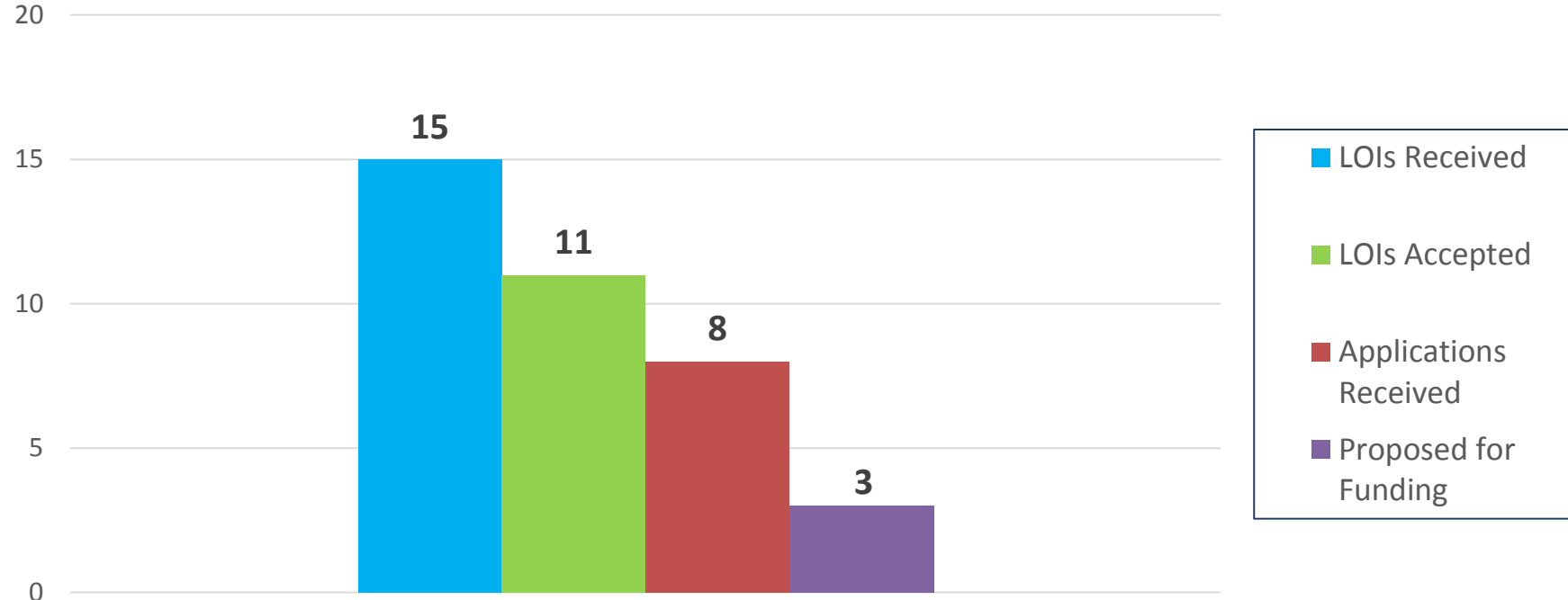
Acting Chief Science Officer

# Cycle 2 2018 – Psychosocial Interventions with Office-Based Opioid Treatment for Opioid Use Disorders Targeted PFA Process Overview



- 15 Letters of Intent (LOIs) received
- 11 LOIs invited to submit a full application
- 8 applications were received
- We are proposing to fund 3 applications\* out of 8 received applications

## Funding rate is 38 percent



# Cycle 2 2018 – Psychosocial Interventions with Office-Based Opioid Treatment for Opioid Use Disorders Targeted PFA

## Slate of 3 Recommended Projects



Project Title
Comparative Effectiveness of Family-Enhanced OBOT and OBOT in Primary Care
Identifying Optimal Psychosocial Interventions for Patients Receiving Office-Based Buprenorphine
Contingency Management to Enhance Office-Based Buprenorphine Treatment for Opioid Use Disorder

### Resubmissions in Bold

Note: All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract

# Project 1: Comparative Effectiveness of Family-Enhanced OBOT and OBOT in Primary Care



- **Research Question:** What is the comparative effectiveness of office-based opioid treatment (OBOT) with Community Reinforcement and Family Training (CRAFT) versus OBOT alone at community health centers?
- **Population:** Predominantly low-income, uninsured adults with opioid use disorder (OUD) in urban areas, who have family support (i.e.: cohabitating spouse, partner, parent, family member, close friend)
- **Comparator(s):**
  - OBOT (usual care - buprenorphine and medication management)
  - OBOT + CRAFT
- **Outcomes of Interest:**
  - Primary: Buprenorphine adherence
  - Secondary: Opioid abstinence, substance use, employment status, mental health, relationship quality, quality of life and other patient/patient-and-partner-reported outcomes
- **Potential Impact:** CRAFT can be readily implemented in low-resource community health settings, using patient-identified family support to improve outcomes for both patient and family member. Results may increase treatment options and improve outcomes for low-income patients with OUD

# Project 2: Identifying Optimal Psychosocial Interventions for Patients Receiving Office-Based Buprenorphine



- **Research Question:** Which psychosocial intervention strategies, alone or combined, are best for helping adults with opioid use disorder (OUD) receiving office-based opioid treatment (OBOT) abstain from opioid use?
- **Population:** Predominantly racial/ethnic minority adults with OUD living in urban areas
- **Comparator(s):**
  - OBOT (usual care - buprenorphine and medication management)
  - OBOT + cognitive behavioral therapy (CBT)
  - OBOT + Peer Support from Certified Recovery Specialist (CRS)
  - OBOT + CBT + CRS
- **Outcomes of Interest:**
  - Primary: Opioid abstinence
  - Secondary: Buprenorphine adherence, substance use, treatment satisfaction, quality of life, and other patient-reported outcomes; provider job satisfaction/stress
- **Potential Impact:** This study will determine which treatment intensity level is appropriate for which patients; results may inform more individualized treatment selection and improve outcomes

# Project 3: Contingency Management to Enhance Office-Based Buprenorphine Treatment for Opioid Use Disorder



- **Research Question:** What is the comparative effectiveness of office-based buprenorphine treatment with remotely-delivered contingency management (CM) versus usual care OBOT?
- **Population:** Predominantly low-income adults, racial/ethnic minorities
- **Comparator(s):**
  - OBOT (usual care - buprenorphine and medication management)
  - OBOT + CM for buprenorphine adherence
  - OBOT + CM for buprenorphine adherence and for opiate abstinence
- **Outcomes of Interest:**
  - Primary: Buprenorphine adherence, opioid abstinence
  - Secondary: Buprenorphine diversion, opioid overdose, psychosocial functioning, quality of life, and other patient-reported outcomes
- **Potential Impact:** Remote delivery of contingency management targets adherence and abstinence directly; payers and health systems can implement this evidence-based intervention directly without added burden for OBOT providers

# Cycle 2 2018 – Psychosocial Interventions with Office-Based Opioid Treatment for Opioid Use Disorders Targeted PFA

## Slate of 3 Recommended Projects\*



<b>PFA</b>	<b>Amount Budgeted</b>	<b>Proposed Total</b>
<b>Cycle 2 2018 Psychosocial Interventions with Office-Based Opioid Treatment for Opioid Use Disorder</b>	<b>\$20M</b>	<b>\$14.9M</b>

\* All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract



## Call for a Motion to:

- **Approve** funding for the recommended award slate from the Cycle 2 2018 Psychosocial Interventions with Office-Based Opioid Treatment for Opioid Use Disorder PFA

## 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

# Wrap Up and Adjournment

 202.827.7700

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 @pcori

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