



# WRITING GRANTS TO PCORI

February 15, 2017



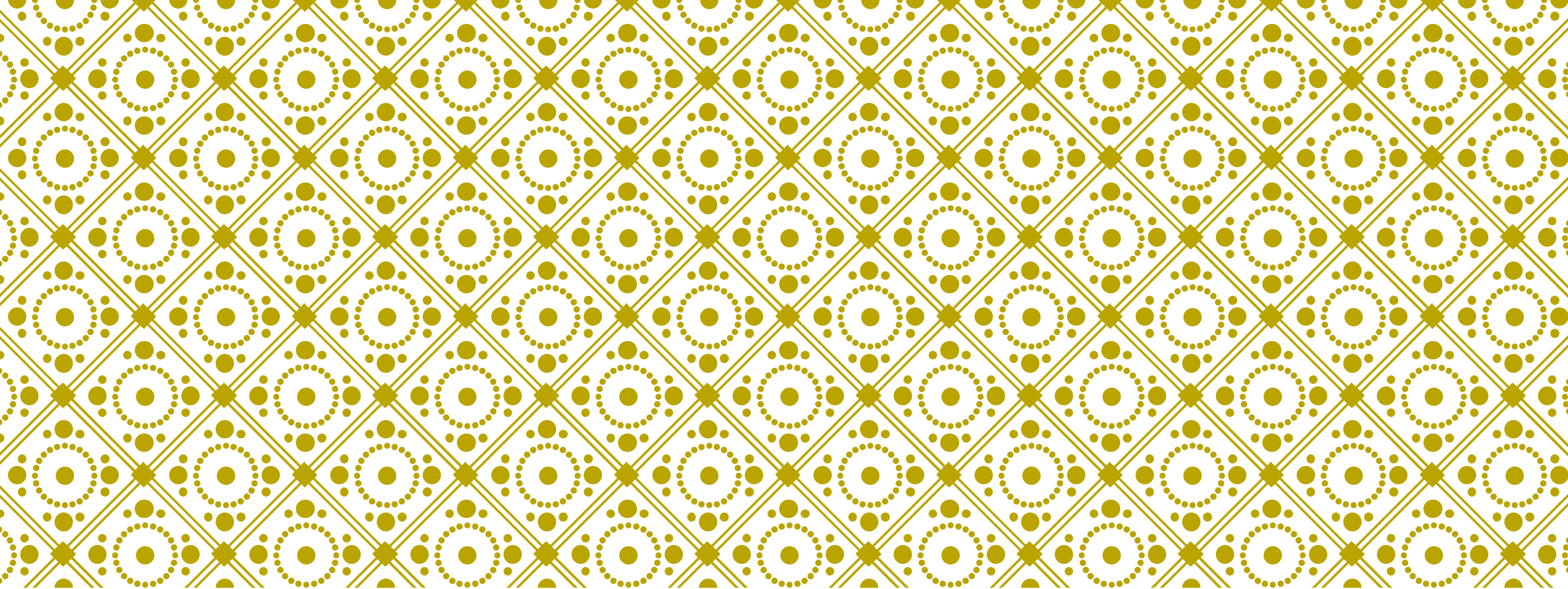
# OBJECTIVES

Understand the PCORI Application Process

Explore PCORI Funding Opportunities

Understand the use of PCORI Methodology Standards

Understand the process of engaging with a PCORI Program Officer



# PCORI APPLICATION PROCESS



# FROM LOI TO FUNDING...

## Step 1:

Decide which PFA to apply for



Topics
Assessment of Prevention Diagnosis and Treatment Options
Addressing Disparities
Communication and Dissemination Research
Improving Healthcare Systems
Improving Methods for Conducting PCOR
Pragmatic Clinical Studies to Evaluate Patient-Centered Outcomes
Dissemination and Implementation of PCORI Funded Patient-Centered Outcomes Research Results and Products in Real World Settings
Pragmatic Clinical Studies to Evaluate Patient-Centered Outcomes

# FROM LOI TO FUNDING...

## Step 1:

Decide which PFA to apply for

## Step 2:

Submit Your LOI (online)



Broad PFA Template
Specific Aims
Background
Significance
Study Design
Engagement approach
Study population and setting
Comparators
Outcome
Analytic plan
Sample size and power

# FROM LOI TO FUNDING...

**PCORI Program Officer #1**      **PCORI Program Officer #2**

**Step 1:**

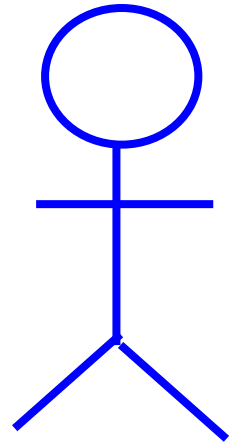
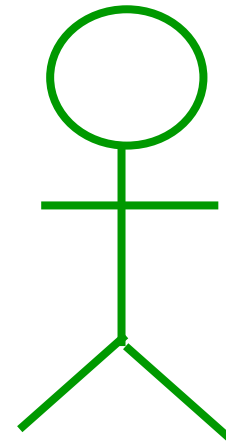
Decide which PFA to apply for

**Step 2:**

Submit Your LOI (online)

**Step 3:**

LOI Review Process



Consider:  
Program Fit  
Current Funding Portfolio  
CER?  
*40 day process*



# FROM LOI TO FUNDING...

## **Step 1:**

Decide which PFA to apply for

## **Step 2:**

Submit Your LOI (online)

## **Step 3:**

LOI Review Process

## **Step 4:**

If invited, submit Full Proposal (online)

## Research Plan Template

Background

Significance

Study Design

Patient Population

Recruitment Plan

Research Team and Environment

Engagement Plan

Dissemination and Implementation  
Potential

Protection of Human Subjects



# FROM LOI TO FUNDING...

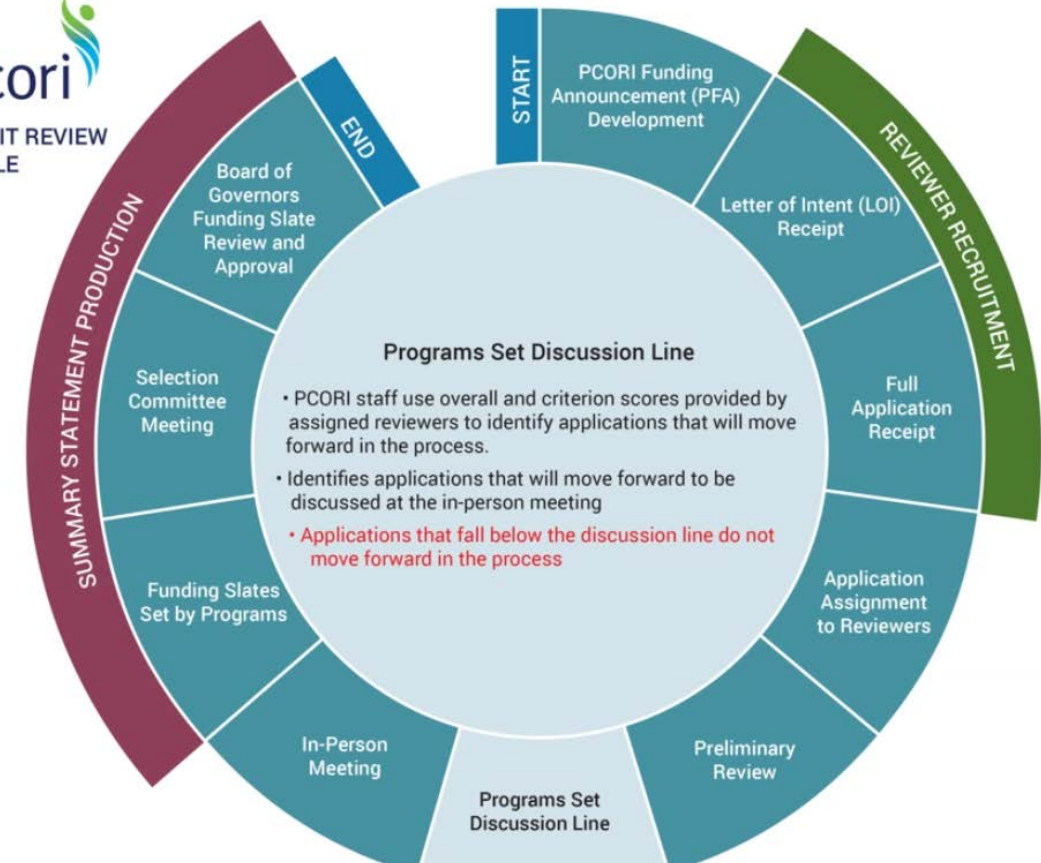
**Step 1:**  
Decide which PFA to apply for

**Step 2:**  
Submit Your LOI (online)

**Step 3:**  
LOI Review Process

**Step 4:**  
If invited, submit Full Proposal (online)

**Step 5:**  
Merit Review





# FROM LOI TO FUNDING...

**Step 1:**  
Decide which PFA to apply for

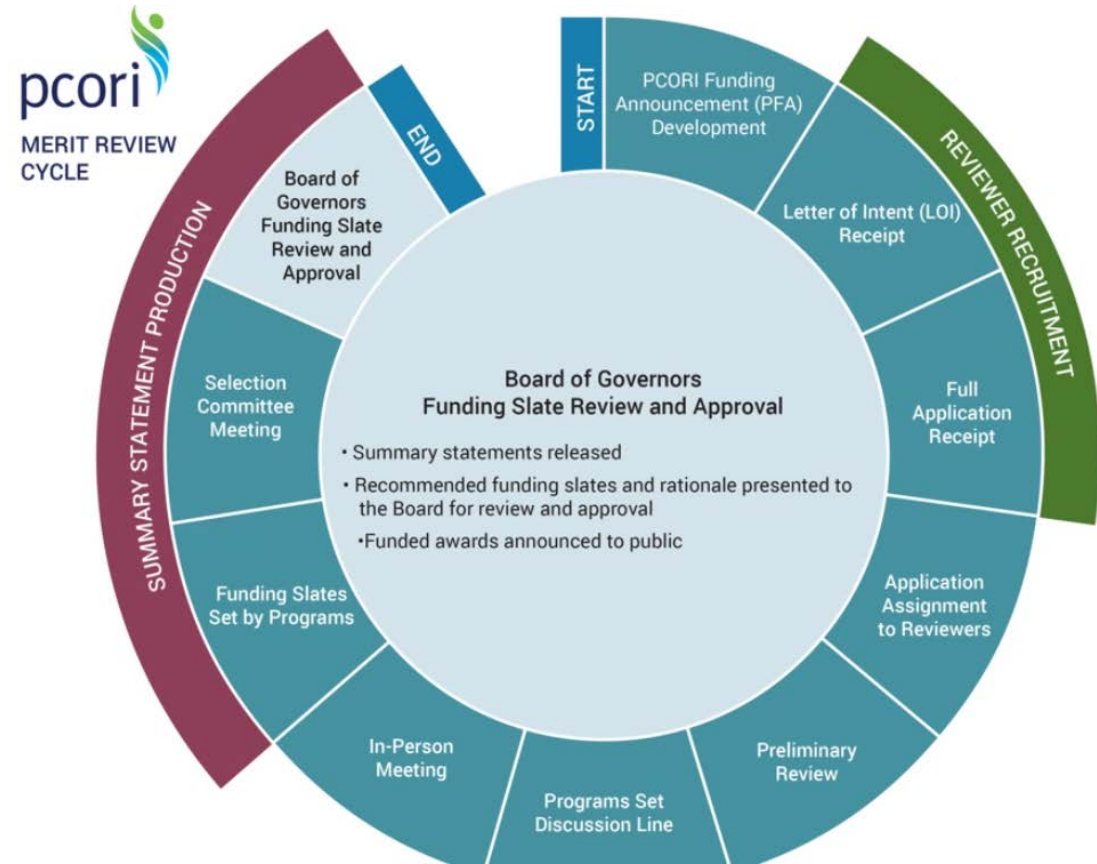
**Step 2:**  
Submit Your LOI (online)

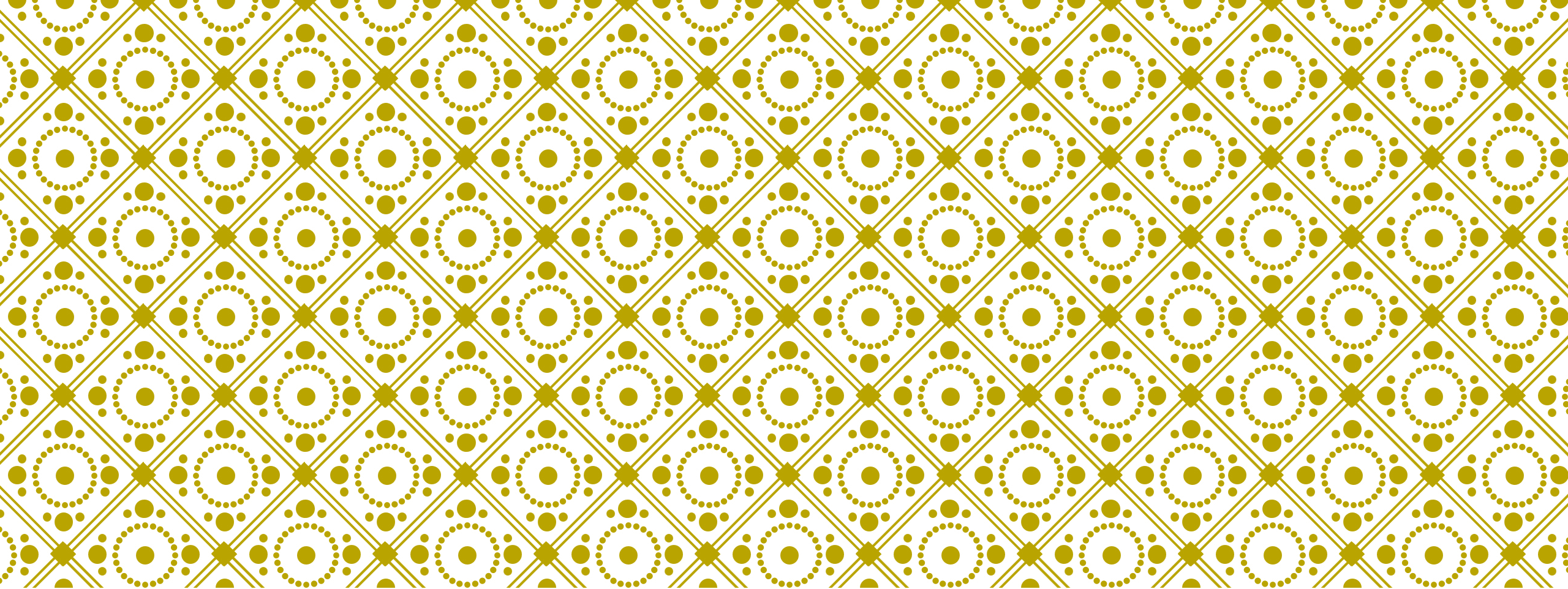
**Step 3:**  
LOI Review Process

**Step 4:**  
If invited, submit Full Proposal (online)

**Step 5:**  
Merit Review

**Step 6:**  
Funding Decision





# PCORI FUNDING OPPORTUNITIES



# FUNDING TOPICS

<u>Topic</u>	<u>General Information</u>	<u>Previously funded example</u>
<b>Addressing Disparities</b>	<p>This funding mechanism supports Comparative Effectiveness Research (CER) studies that <b>specifically evaluate, compare, and identify the most effective inventions to reduce or eliminate disparities in health and health care.</b> Proposed studies should be focused on previously understudied populations and work towards overcoming barriers that disproportionately affect health outcomes in these target populations.</p>	<ul style="list-style-type: none"> <li>• Pain Coping Skills Training For African Americans with Osteoarthritis</li> </ul>
<b>Assessment of Prevention Diagnosis and Treatment Options</b>	<p>This funding will support <b>CER studies designed to inform critical decisions facing patients, caregivers, clinicians, policy makers, healthcare system leaders.</b> This is a very broad-based funding mechanism that can include investigations of many different things relating to prevention, diagnosis, and treatment options. Critically, there must be a comparison of at least two alternative approaches.</p>	<ul style="list-style-type: none"> <li>• Comparative Effectiveness of Rehabilitation Interventions for Traumatic Brain Injury</li> </ul>
<b>Communication and Dissemination Research</b>	<p>This funding mechanism is designed to support CER studies of communication and dissemination strategies. <b>These studies would help identify the most effective strategies to improve communication/dissemination of research results to patients, their caregivers, and clinicians as well as improve communication between patients, caregivers, and clinicians.</b> These strategies would need to create highly informed and empowered participants so that optimal shared decision making can be achieved.</p>	<ul style="list-style-type: none"> <li>• Resetting the Default: Improving Provider-Patient Communication to Reduce Antibiotic Misuse</li> </ul>

# FUNDING TOPICS

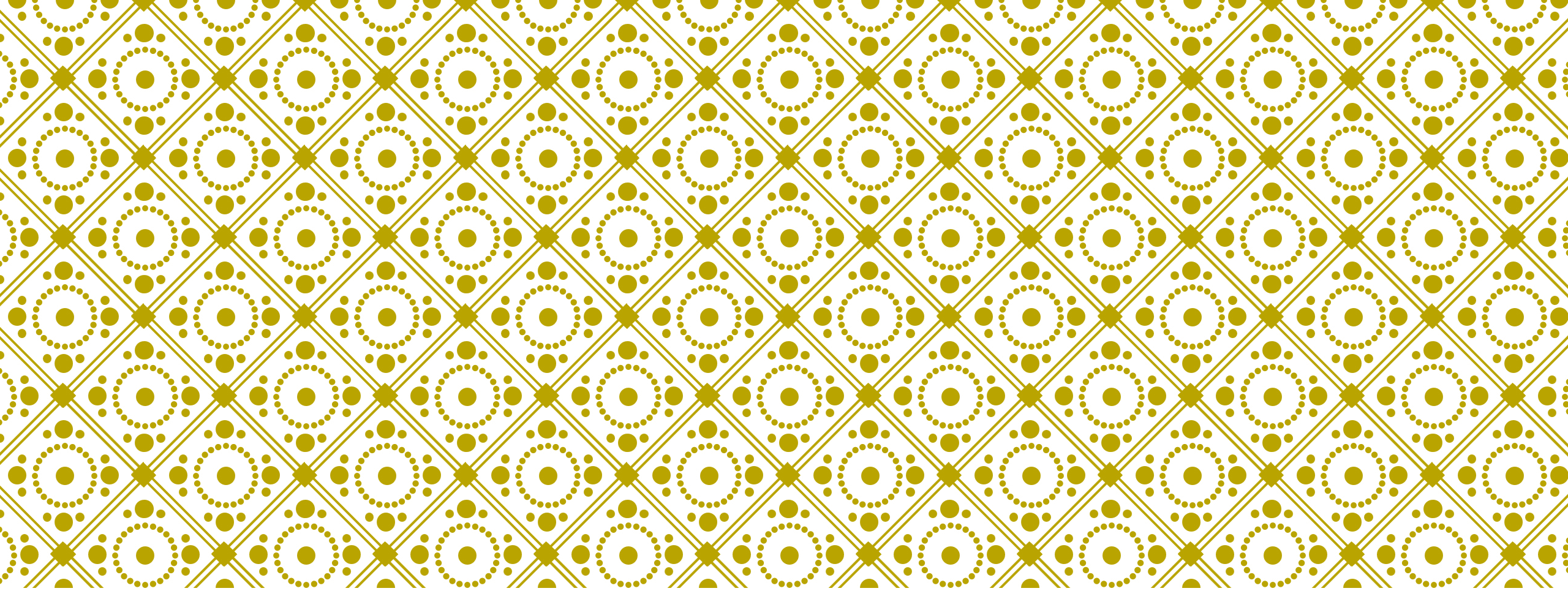
<u>Topic</u>	<u>General Information</u>	<u>Previously funded example</u>
<b>Improving Health Care Systems</b>	This funding opportunity focuses on <b>CER studies of alternative features of healthcare systems that are intended to optimize the quality, outcomes, and efficiency of patient care</b> and well as those features that have the greater potential for impact and replication across healthcare systems. The results of these studies would ideally be able to inform system-level changes.	<ul style="list-style-type: none"> <li>Improving Care Coordination for Children with Disabilities through an Accountable Care Organization</li> </ul>
<b>Improving Methods for Conducting PCOR</b>	This funding mechanism specifically funds methodological research relevant to CER and Patient-Centered Outcomes Research (PCOR). <b>These studies will focus on identifying the best methods, practices, and standards for CER and PCOR.</b> This has been an high investment topic for PCORI and thus many projects have been previously funded. As such, PCORI has decided to have a narrower set of program priorities so be sure to check if your proposed project aligns with the most current priorities.	<ul style="list-style-type: none"> <li>Developing and Validating Quantitative Measures to Assess Community Engagement in Research</li> </ul>
<b>Pragmatic Clinical Studies to Evaluate Patient-Centered Outcomes</b>	This funding will support large <b>pragmatic clinical trials, large simple trials, or large-scale observational studies</b> that will investigate two or more comparators as it relates to prevention, diagnosis, treatment, or management of a disease. This funding mechanism <u>also supports</u> trials investigating comparators in healthcare systems, communication, dissemination, and eliminating health or healthcare disparities. Please note, this does not support randomized controlled clinical trials (RCT).	<ul style="list-style-type: none"> <li>Integrated Smoking Cessation Treatment for Smokers with Serious Mental Illness</li> </ul>

# FUNDING OPPORTUNITIES 2017

Cycle	LOI Due Date	Proposal Due Date	Topics
1	2/14/2017	5/17/2017	Assessment of Prevention Diagnosis and Treatment Options
			Addressing Disparities
			Communication and Dissemination Research
			Improving Healthcare Systems
			Improving Methods for Conducting PCOR
			Pragmatic Clinical Studies to Evaluate Patient-Centered Outcomes
			Dissemination and Implementation of PCORI Funded Patient-Centered Outcomes Research Results and Products in Real World Settings
			Comparison of Surgical and Nonsurgical Options for Management of Chronic Nonspecific Low Back Pain
			Optimal Treatment Sequences for Nonspecific Chronic Low Back Pain
2	7/25/2017	10/25/2017	Pragmatic Clinical Studies to Evaluate Patient-Centered Outcomes
			Dissemination and Implementation of PCORI Funded Patient-Centered Outcomes Research Results and Products in Real World Settings

# FUNDING OPPORTUNITIES 2017

Cycle	LOI Due Date	Proposal Due Date	Topics
3	10/31/2017	2/6/2018	Assessment of Prevention Diagnosis and Treatment Options
			Addressing Disparities
			Communication and Dissemination Research
			Improving Healthcare Systems
			Improving Methods for Conducting PCOR
			Pragmatic Clinical Studies to Evaluate Patient-Centered Outcomes
			Dissemination and Implementation of PCORI Funded Patient-Centered Outcomes Research Results and Products in Real World Settings



# **PCORI METHODOLOGY STANDARDS**



# OVERVIEW

The Methodology Standards specify the minimal requirements for best practices in the design and conduct of PCOR

As of PCORI's August 2013 funding cycle, all applicants must show that they follow the standards

The 47 standards fall broadly into two groups:

- Cross-cutting standards for PCORI
- Standards for specific study designs and methods

However, the standards are currently being revised so an updated set is expected in 2017

<http://www.pcori.org/research-results/research-methodology/pcori-methodology-standards>



# CROSS-CUTTING STANDARDS FOR PCOR

## Formulating research questions

- Six (6) standards that specify what to include in research protocols to increase study quality and transparency

## Patient-centeredness

- Four (4) standards that promote effective patient engagement and the explicit incorporation of patient needs, values, and preferences into research

## Data integrity and rigorous analysis

- Six (6) standards that describe necessary documentation of key decisions and tests of the assumptions made in analysis

## Preventing and handling missing data

- Five (5) standards outlining proper statistical methods for handling missing data

## Heterogeneity of treatment effects (HTE)

- Four (4) standards on accounting for the fact that different people do not always respond the same way to the same treatment

# STANDARDS FOR SPECIFIC STUDY DESIGNS & METHODS

## Data registries

- Three (3) standards to help ensure that registries contain relevant, high-quality data that are used appropriately

## Data networks as research-facilitating infrastructures

- Two (2) standards to help ensure that key components are included in network design and considered when network data are used in studies

## Casual inference methods

- Six (6) standards on accounting for possible sources of bias and addressing them to produce valid conclusions about the causal effect of an intervention

## Adaptive and Bayesian trial designs

- Five (5) standards providing guidance on the design and conduct of studies that use such designs

## Studies of diagnostic tests

- Five (5) standards that address studying the impact of diagnostic tests on subsequent care and patient outcomes

## Systematic reviews

- One (1) standard that outlines the application of standards for systematic reviews

# CLOSER LOOK: STANDARDS FOR FORMULATING RESEARCH QUESTIONS

## 1: Standards for Formulating Research Questions

### **RQ-1: Identify gaps in evidence**

Gap analysis and systematic reviews should be used to support the need for a proposed study. If a systematic review is not available, a systematic review should be performed using accepted standards in the field (see standard SR-1), or a strong rationale should be presented for proceeding without a systematic review. In the case where a systematic review is not possible, the methods used to review the literature should be explained and justified.

### **RQ-2: Develop a formal study protocol**

Studies should include a formal protocol specifying at least one purpose for which the data were collected (e.g., effectiveness, safety, natural history of disease, quality improvement); data sources and linkage plans, if any; data feasibility and quality, measure(s) of effect; and use of any standardized data dictionaries (nationally or internationally accepted).

### **RQ-3: Identify specific populations and health decision(s) affected by the research**

To produce information that is meaningful and useful to people when making specific health decisions, research proposals and protocols should describe: 1) the specific health decision the research is intended to inform; 2) the specific population for whom the health decision is pertinent; and 3) how study results will inform the health decision.

# CLOSER LOOK: STANDARDS FOR FORMULATING RESEARCH QUESTIONS

## **RQ-4: Identify and assess participant subgroups**

In designing studies, researchers should identify participant subgroups of interest and, where feasible, design the study with adequate precision and power to reach conclusions specific to these subgroups. In addition, subgroup information should be reported for later systematic reviews.

## **RQ-5: Select appropriate interventions and comparators**

When evaluating an intervention, the comparator treatment(s) must be chosen to enable accurate evaluation of effectiveness or safety compared to other viable options for similar patients. Researchers should make explicit what the comparators are and how they were selected, focusing on clearly describing how the chosen comparator(s) define the causal question, reduce the potential for biases, and allow direct comparisons. Generally, non-use (or no specific treatment) comparator groups should be avoided unless no specific treatment is a likely option in standard care.

## **RQ-6: Measure outcomes that people representing the population of interest notice and care about**

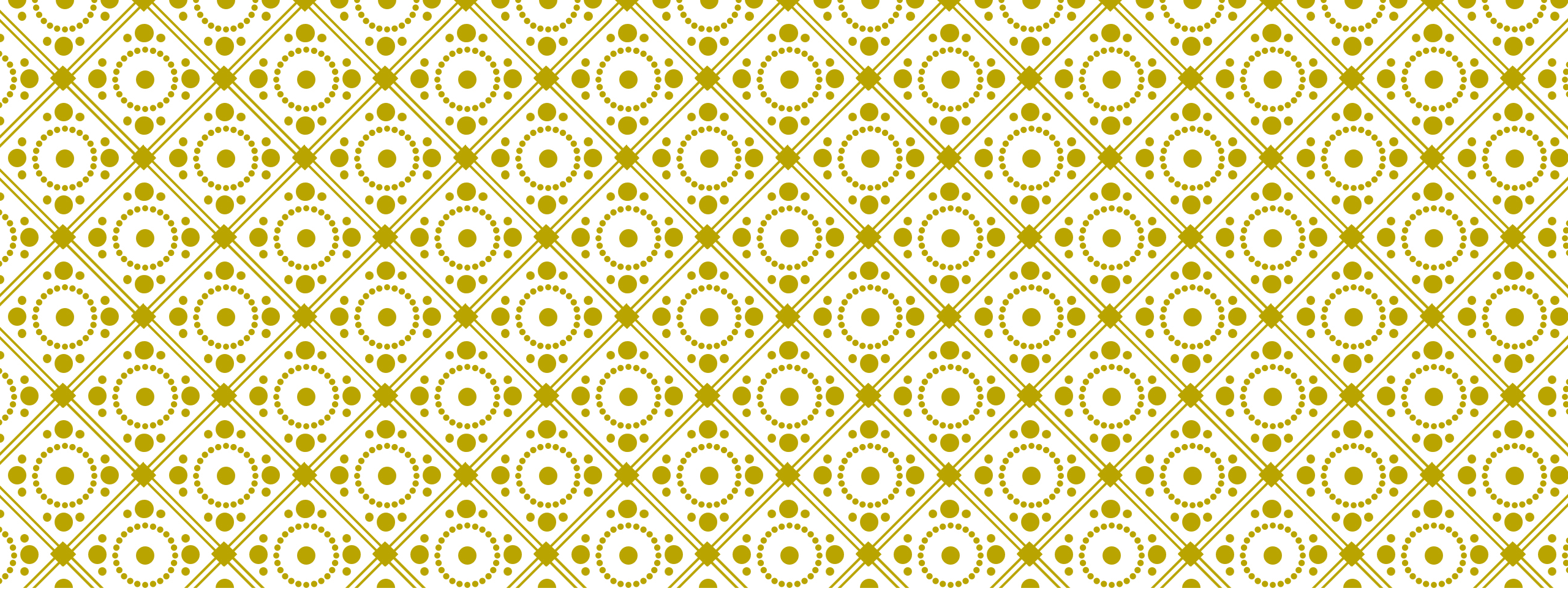
Identify and include outcomes the population of interest notices and cares about (e.g., survival, function, symptoms, health-related quality of life) and that inform an identified health decision. Define outcomes clearly, especially for complex conditions or outcomes that may not have established clinical criteria. Provide information that supports the selection of outcomes as meeting the criteria of “patient-centered” and “relevant to decision makers,” such as patient and decision-maker input from meetings, surveys, or published studies. Select outcomes based on input directly elicited from patient informants and people representative of the population of interest, either in previous studies or in the proposed research.

# INCORPORATING STANDARDS INTO GRANTWRITING

## Background

- *Describe the impact of the condition on the health of individuals and populations. (Criterion 1. Potential for the study to fill critical gaps in evidence)*
- *Identify gaps in evidence. (RQ-1)*

Drug X and Drug Y has each been shown to be highly efficacious treatment options for treating diabetes. However, systemic reviews has revealed there is limited evidence of which of these treatment options is most effective in rural health clinics spanning the Southwest United States (RQ-1).



# ENGAGING WITH PCORI PROGRAM OFFICERS

# TIPS FOR ENGAGING PCORI PROGRAM OFFICERS

- Before Engaging a Program Officer:
  - Determine your **CER question**
    - Partnership-wide effort
    - Engage with PAPO staff to determine where potential CER ideas may be a good fit for PCORI
  - Prepare
    - Identify which PFAs may be most appropriate for your CER question
    - Outline Specific Aims, Study Design, Outcomes
      - Rough ideas are ok, important to get a general outline together of your proposal

# TIPS FOR ENGAGING PCORI PROGRAM OFFICERS

- Contact PCORI
  - Email: [sciencequestions@pcori.org](mailto:sciencequestions@pcori.org)
  - Inquiry form: [pcori.org/content/research-inquiry](https://pcori.org/content/research-inquiry)
  - Call: 202-627-1884
- Engage
  - Assigned a Program Officer contact
  - Opt for in-person discussions when offered!
  - Follow up as needed, but remember Program Officers will not guide your proposal and will not be a full-time resource





**QUESTIONS?**