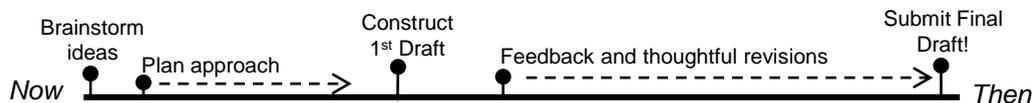


# Planning a Letter of Intent (LOI) Submission to PCORI and Beyond

With one of the major deliverables in Tier III being a LOI submission to PCORI, your partnership should be starting to plan how to work together to produce a well-crafted LOI.

In a **perfect world**, the timeline to submission looks like this....



But in **reality**, it's more like this....



To reduce stress and scramble, this guide was designed to be shared with your partnership in order to encourage planning for a partnership-engaged approach to submitting LOIs to PCORI and other funding organizations. Sections were divided in order to provide the most useful information across all levels of LOI-writing experience.

If you would say that...	I'm new to writing LOIs, let's start at the beginning	I've written LOIs before but not for PCORI	I'm experienced with LOIs to PCORI and elsewhere. What's the bottom line?
Look for this symbol to find the most helpful sections			

## Section 1: LOI on LOIs (Lots of Information on Letters of Intent)



### LOI Basics

*What is an LOI and why do I have to submit one?*

- An LOI refers to a Letter of Intent, also known as a Letter of Interest or Letter of Inquiry
- LOI are non-legally binding documents that serve to express your interest in a particular funding opportunity. They can also function to introduce you and your organization to a funding organization
- The main purpose of an LOI is to allow for the funding organization to determine if there is a good match between what you are proposing to do and what they are looking to fund. If they determine there is a good match, they will invite you to submit a full application
- Funding organizations also use LOIs to get a sense of how many applications they are going to receive in order to plan the review process
- LOIs need to be brief and concise (1-3 pages max) while also including all the critical information necessary to make your case to the funding organization----- a simple statement to say but a much harder task to achieve!

# LOI Components

What do I need to include?

- LOI requirements are going to differ from funder to funder and from announcement to announcement. In general, each LOI needs to contain the following information:

Who are you?	<ul style="list-style-type: none"> <li>• Basic contact information for you and your organization</li> <li>• Qualifications that make you/partnership/organization well-equipped to successfully execute the proposed work</li> </ul>
What are you going to do?	<ul style="list-style-type: none"> <li>• Explain your proposed project, including all relevant background information, the identified problem, your proposed solution, methodology, timelines, etc.</li> </ul>
How does this improve things?	<ul style="list-style-type: none"> <li>• Opportunity for you to express how your study addresses a critical knowledge gap, what the greater impact of your study could be, and possible future implications</li> </ul>
How much is it going to cost?	<ul style="list-style-type: none"> <li>• Brief overview of proposed budget</li> </ul>
Why is this a good fit for the funder?	<ul style="list-style-type: none"> <li>• Make the case for why your proposed project is the perfect match for their funding opportunity. This element should be incorporated throughout the LOI and clear to the funder</li> </ul>

Here are some **non-PCORI** funding announcements where we can break down the requirements into the basic LOI components listed above



**California Health Care Foundation**

**Letters of Inquiry:**  
A letter of inquiry should be one to three pages long and include:

1. A brief description of the proposed project
2. A description of how the project fits with the programmatic work of the foundation, including under which strategic goal it fits
3. An estimated timeline
4. The amount requested
5. Contact information

## LOI Guidelines from a Foundation

What are you going to do?

Why is this a good fit for the funder?

How does this improve things?

What are you going to do?

How much it is going to cost?

Who are you?

## LOI Guidelines from a University Institute

### Duke Clinical & Translational Science Institute

The Review Committee will consider the following criteria when reviewing and scoring applications:

- Significance – The novelty, uniqueness and impact of the opportunity presented by the proposal; opportunities that provide generalizable solutions to translational research problems are highly encouraged.
- Approach – Methods and analyses used are well-reasoned and suitable to complete value recognition studies and proposed specific aims.
- Feasibility – Project scope of work is appropriate for the timeframe and level of funding.
- Collaboration – Collaboration of investigators provides complementary skills and expertise.
- Translation – Translational potential of the opportunity including intellectual property, strategy for partnering and follow-on support where needed to advance the proposed activity.

How does this improve things?

What are you going to do?

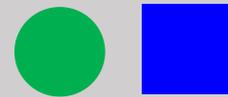
How much is this going to cost?

Who are you?

How does this improve things?

Why is this a good fit for the funder?

**Special Note:** If there are no templates or guidelines provided, you will need to construct your LOI in a letter format that includes all the basic LOI components. For great guidelines on how to organize these types of LOIs, visit [here](#) or [here](#)



# Section 2: Planning for PCORI-specific LOIs

## PCORI Funding Opportunities

What topic should I write my LOI for?

- PCORI has historically offered three cycles of funding competition each year with the number of specific topics varying across the cycles. This guide will focus on **Cycle 1 2017**, as this is most relevant for your Tier III deliverable. However, keep in mind the other cycles listed on the [schedule](#)
- The topics listed for the Cycle 1 2017 (all due **Feb 14, 2017**) funding competition are as follows:

<u>Topic</u>	<u>General Information</u>	<u>Previously funded example</u>
<b>Addressing Disparities</b>	This funding mechanism supports Comparative Effectiveness Research (CER) studies that specifically evaluate, compare, and identify the most effective inventions to reduce or eliminate disparities in health and health care. Proposed studies should be focused on previously understudied populations and work towards overcoming barriers that disproportionately affect health outcomes in these target populations.	<ul style="list-style-type: none"> <li>• Pain Coping Skills Training For African Americans with Osteoarthritis</li> <li>• More listed <a href="#">here</a></li> </ul>
<b>Assessment of Prevention Diagnosis and Treatment Options</b>	This funding will support CER studies designed to inform critical decisions facing patients, caregivers, clinicians, policy makers, healthcare system leaders. 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.	<ul style="list-style-type: none"> <li>• Comparative Effectiveness of Rehabilitation Interventions for Traumatic Brain Injury</li> <li>• More listed <a href="#">here</a></li> </ul>
<b>Communication and Dissemination Research</b>	This funding mechanism is designed to support CER studies of communication and dissemination strategies. 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. These strategies would need to create highly informed and empowered participants so that optimal shared decision making can be achieved.	<ul style="list-style-type: none"> <li>• Resetting the Default: Improving Provider-Patient Communication to Reduce Antibiotic Misuse</li> <li>• More listed <a href="#">here</a></li> </ul>
<b>Improving Health Care Systems</b>	This funding opportunity focuses on CER studies of alternative features of healthcare systems that are intended to optimize the quality, outcomes, and efficiency of patient care 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> <li>• More listed <a href="#">here</a></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). These studies will focus on identifying the best methods, practices, and standards for CER and PCOR. 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> <li>• More listed <a href="#">here</a></li> </ul>
<b>Pragmatic Clinical Studies to Evaluate Patient-Centered Outcomes</b>	This funding will support large pragmatic clinical trials, large simple trials, or large-scale observational studies 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> <li>• More listed <a href="#">here</a></li> </ul>

# PCORI LOI Templates

What do I need to include?

- For each funding opportunity, there is a unique LOI template that contains a series of questions designed to gauge whether your proposed project is a good fit for that specific funding topic
- While the composition of each template is different, there are **several important components that are shared** across templates. These include:

PCORI LOI Component	Basic LOI Component (Section 1)	Overview	Suggested Lead Partner
<b>Specific Aims</b>  Also referred to as: <i>Objectives</i>	<p>What are you going to do?</p> <p>Why is this a good fit for the funder?</p>	This is where you explain exactly what you set out to do in your CER project. Specific Aims should be clear, concise, and most importantly, quickly excite the reviewers about your proposal.	<u>All partners</u> should be involved in deciding and refining the specific aims section
<b>Gap Analysis</b>  Also referred to as: <i>Background Evidence Gap</i>	<p>How does this improve things?</p>	The Gap Analysis section allows you to set the stage for why your study is going to provide novel information that addresses a critical problem. In this section, you will review the relevant background to your research question and highlight the missing information (aka ‘evidence gap’) that prevents solving your specific problem. Your specific aims and study design should be constructed in a way that clearly demonstrates how your results will fill this evidence gap.	With an extensive knowledge of the current literature needed, the <u>research partners</u> should spearhead this section
<b>Decisional Dilemma</b>  Also referred to as: <i>Decisional Uncertainty Decision</i>	<p>How does this improve things?</p>	This section requires you to describe the specific clinical decision or treatment choice confronted by a decision maker (i.e. patient, clinician, caregiver, etc.) in regards to the issue addressed by your proposal. While there may be some overlap between this section and the Gap Analysis section, it is important to emphasize the clinical perspective and the real-world circumstances that maintain this decisional dilemma.	This is a great section for your <u>stakeholder partners</u> to take the lead on
<b>Study Design</b>  Also referred to as: <i>Methods</i>	<p>What are you going to do?</p>	This section is the roadmap, the manual, the blueprint of your whole project. Here you need to convince reviewers that you have a reasonable and feasible plan to go from the identified problem to the proposed solution. <b>Useful P2P Deliverable:</b> CER question grid	With so many moving parts, <u>all partners</u> should be involved in this section
<b>Comparators</b>	<p>What are you going to do?</p>	Here you will need to describe the list of comparators that you will be testing in your study. Importantly, you need to be able to describe the evidence of efficacy for each comparator as well as an estimate for how frequently each is used in the clinical setting. If you are going to use ‘usual care’ as an comparator, you will need to be able to describe, document, and measure the usual care procedure. Please note, PCORI does not fund any studies that uses a previously untested comparator. <b>Useful P2P Deliverable:</b> CER question grid	While deciding on the comparators is a team effort, the <u>research partners</u> may be best suited to lead this section given the importance of describing the existing literature

<p><b>Outcomes</b></p> <p>Also referred to as: <i>Anticipated Impact</i></p>	<p>How does this improve things? Why is this a good fit for the funder?</p>	<p>This is the section where you describe what the end results will be after your study. You will need to describe your primary outcomes and if necessary, any secondary outcomes. You will need to be able to describe the methods used to measure and validate these outcomes. Also, you should describe how the selected outcomes were determined to be important and relevant to patients.</p> <p><b>Useful P2P Deliverable:</b> CER question grid</p>	<p>This section should be led by the <u>patient partners</u></p>
<p><b>Sample size</b></p> <p>Also referred to as: <i>Power calculations</i></p>	<p>What are you going to do?</p>	<p>This is a very specific section that describes the statistical methodology that determines how many study participants you plan to include in your study in order to collect enough data to be confident in your conclusions.</p>	<p>A <u>biostatistician</u> is critical to accurately complete this section. If there is no biostatistician in your partnership, it would be highly beneficial to consult with one prior to completing this important component of your study</p>
<p><b>Duration and Total Costs</b></p> <p>Also referred to as: <i>Duration of Study</i> <i>Cost of Study</i></p>	<p>What are you going to do? How much is it going to cost?</p>	<p>Here is where you describe the feasible timeline of your proposed study and the associated costs.</p>	<p><u>All partners</u> should contribute to this section with <u>stakeholders</u> leading what constitutes a reasonable timeline</p>
<p><b>Engagement</b></p>	<p>What are you going to do? Why is this a good fit for the funder?</p>	<p>Arguably, this is the core of all PCORI proposals. This is the section where you describe how researchers, patients, and stakeholders are involved in planning, conducting, and disseminating the study. This is what you have been building in the P2P program and it is very important to highlight all of your amazing work!</p> <p><b>Useful P2P Deliverable:</b> The governance document and communication plan will be great resources in developing your engagement plan</p>	<p><u>All partners</u> should be involved in this section</p>

## PCORI LOI Review

### *What happens after I submit?*

- After submission, PCORI will perform an administrative review to make sure there were no errors during the submission process
- The next review involves a small number of PCORI Program Officers (commonly 2) who will review the content of your LOI. They are especially looking for:
  - Is the proposed topic **appropriate** to the funding announcement? In other words, is this a good match?
  - Does the proposed study **complement** the current funded portfolio? This is especially important because if they have previously funded a study similar to the one you are proposing, it is unlikely that they are going to be able to make a similar investment again
  - Is your proposal **scientifically sound**? This is a general assessment as the Program Officers are not likely to be experts in your field. However, they will be able to assess whether you are proposing an appropriate CER question and if the study design is feasible

- As you write your LOI, it is highly important to **keep your target audience in mind** as you build the content. While you want to present a well-crafted and articulate LOI, it is important to keep it accessible to someone who is knowledgeable of your topic but not necessarily an expert. You don't want to overwhelm the LOI with specific details that confuses the reviewer. If you are invited for a full proposal, these applications will be reviewed by a variety of individuals, including experts in the field. As such, you will want to incorporate the more specific and specialized details in the full proposal.
- In order to maximize your chances to advance through LOI review, it is highly encouraged to **contact your PCORI Program Officer** prior to constructing your LOI. Through these conversations, you can gauge whether your proposed study would be a good match for the funding program as well as whether or not it fits within their funding portfolio.

## Section 3: Summary Information for PCORI Funding Opportunities



- Below is a list of Cycle 1 PCORI Funding Opportunities and their respective deadlines. Again, we highly encourage you to contact your Program Officer prior to completing your LOI. You can do this by emailing [sciencequestions@pcori.org](mailto:sciencequestions@pcori.org) or filling out an [inquiry form](#) . To further assist with this, we have provided the emails of potentially helpful PCORI Program Officers. If you would like more guidance on how to approach this conversation or if you want to practice your pitch, please call your Technical Assistance lead at CFPHE. We are happy to help!

<u>Cycle 1 Opportunity</u>	<u>Deadline</u>	<u>Program Officers</u>
Addressing Disparities	2/14/2016	Ayodola Anise, MHS <a href="mailto:aanise@pcori.org">aanise@pcori.org</a> Mira Grieser, MHS <a href="mailto:mgrieser@pcori.org">mgrieser@pcori.org</a> Cathy Gurgol, MS <a href="mailto:cgurgol@pcori.org">cgurgol@pcori.org</a>
Assessment of Prevention, Diagnosis, and Treatment Options*	2/14/2016	Kimberly Bailey, MS <a href="mailto:kbailey@pcori.org">kbailey@pcori.org</a> Laura Esmail, PhD, MSc <a href="mailto:lesmail@pcori.org">lesmail@pcori.org</a> Layla Lavasani, PhD, MHS <a href="mailto:llavasani@pcori.org">llavasani@pcori.org</a> Julie McCormack, MA <a href="mailto:jmccormack@pcori.org">jmccormack@pcori.org</a> Holly Ramsawh, PhD <a href="mailto:hramsawh@pcori.org">hramsawh@pcori.org</a>
Communication and Dissemination Research	2/14/2016	Bridget Gaglio, MPH, PhD <a href="mailto:bgaglio@pcori.org">bgaglio@pcori.org</a> William Lawrence, MD, MS <a href="mailto:wlawrence@pcori.org">wlawrence@pcori.org</a>
Improving Health Care Systems	2/14/2016	Gyasi Moscou-Jackson, PhD, MHS, RN <a href="mailto:gjackson@pcori.org">gjackson@pcori.org</a> Jeanne Murphy, PhD, CNM (no email listed)
Improving Methods for Conducting PCOR	2/14/2016	Emily Evans, PhD, MPH <a href="mailto:eevans@pcori.org">eevans@pcori.org</a> Andrea Heckert, PhD, MPH <a href="mailto:heckert@pcori.org">heckert@pcori.org</a> Danielle Whicher, PhD, MHS <a href="mailto:dwhicher@pcori.org">dwhicher@pcori.org</a>
Pragmatic Clinical Studies to Evaluate Patient-Centered Outcomes	2/14/2016	Sarah Daugherty, PhD MPH <a href="mailto:sdaugherty@pcori.org">sdaugherty@pcori.org</a>

\*Programs officers for Clinical Effectiveness Research listed here