PCORI's Application Submission Process, Preparing a Budget, and Related Programmatic and Administrative Considerations

James Hulbert
Assistant Director, Policy and Planning
Contracts Management and Administration

September 20, 2016

pcori

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Welcome!

James Hulbert,
Assistant Director,
Policy and Planning,
Contracts Management and Administration

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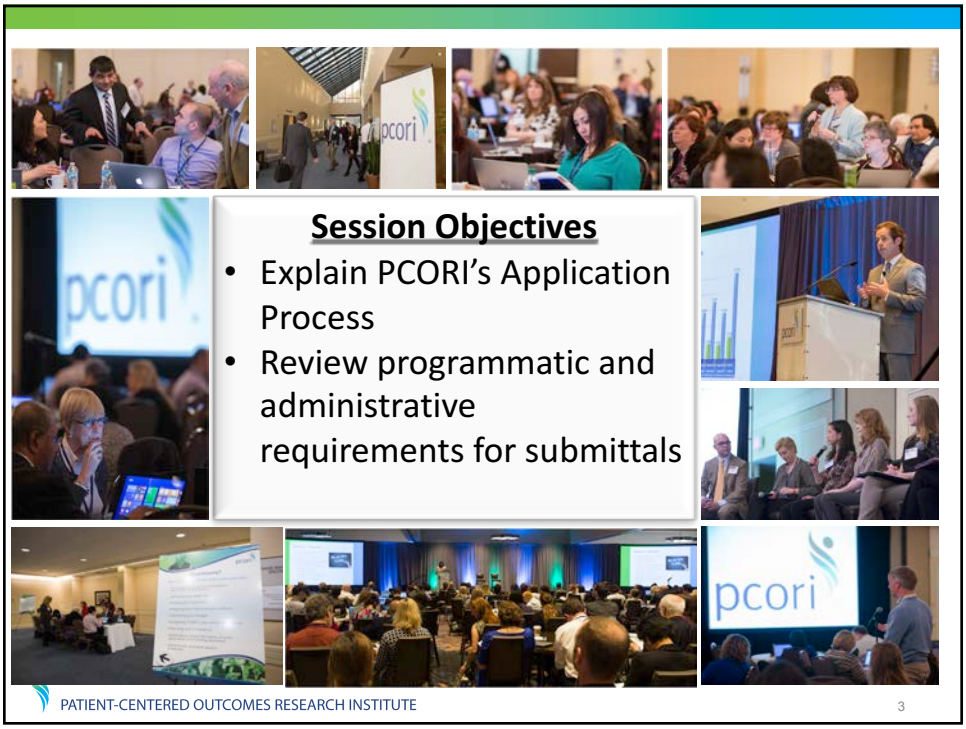
2



Application Requirements: Who Can Apply?

- Any private sector research organization

Non-Profit Organizations **For Profit Organizations**

- Any public sector research organization

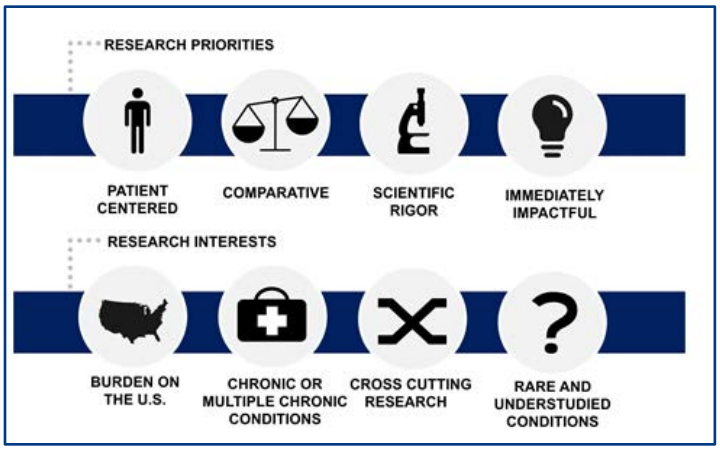
Universities/ Colleges **Hospitals or Healthcare Systems** **Local, State, or Federal Government** **Laboratories**

- Foreign Organizations
- Nondomestic Components of Organizations based in US

NOTE

PI **must** be an employee of the prime applicant institution. Individuals are not eligible to submit research applications to PCORI.

What Does PCORI Look For in Applications?



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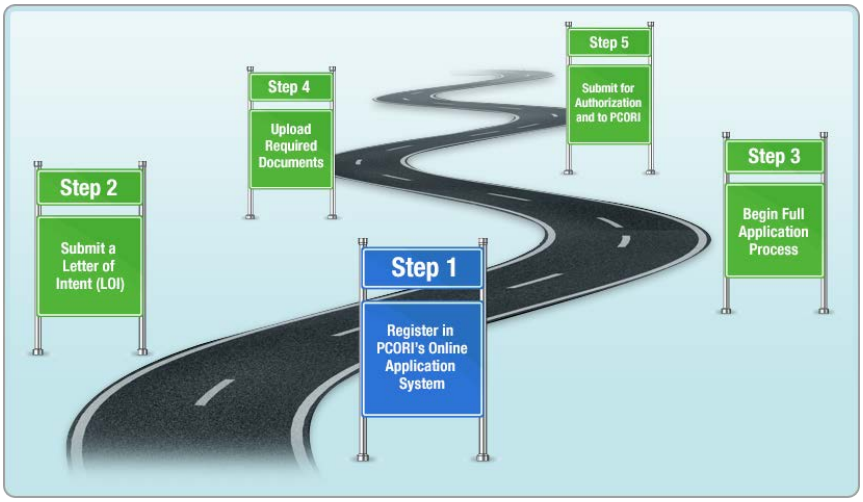
5

PCORI's Online Application Process



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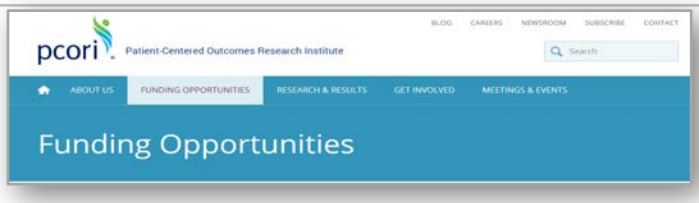
The PCORI Funding Center



Contains details about:

- PCORI's Application Process
- Key dates and deadlines
- How to access PCORI's Online Application System and build an application
- PCORI's application guidelines, checklists, and templates
- Access to training webinars

NOTE

Be sure to download templates for the cycle you are submitting to.

Upcoming Funding Opportunities

Cycle	Funding Opportunity	PCORI Online Opens	LOI Due	Full Application Due	Merit Review Meeting	Awards Announced
Cycle 3 2016	AD	August 15, 2016	September 14, 2016	December 19, 2016	March 2017	June 2017
	APDTO					
	CDR					
	D&I					
	IHS					
	Methods					
	Palliative Care					
	PCS					
	SCD					
	Unsafe Opioids Prescribing					
MS/Opioids	MS/Opioids	October 4, 2016	November 1, 2016	February 7, 2017	June 2017	August 2017
Cycle 1 2017	AD	February 6, 2017	March 8, 2017	June 12, 2017	September 2017	November 2017
	APDTO					
	CDR					
	D&I					
	IHS					
	Methods					
	PCS					

PFA Overview

PCORI Funding Announcement	Funding Per Cycle	Direct Cost Cap	Project Duration	Greater Than
Assessment of Prevention, Diagnosis and Treatment Options	$32 Million	$2,000,000	3 Years	No
Improving Healthcare Systems	$16 Million	$5,000,000 *(large)*	5 Years	No
		$1,500,000 *(small)*	3 Years	No
Communication and Dissemination Research	$8 Million	$1,500,000	3 Years	Yes (Time and Budget)
Addressing Disparities	$8 Million	$1,500,000	3 Years	No
Improving PCORI Methods	$12 Million	$750,000	3 Years	No
Pragmatic Clinical Studies	$90/$80 Million	$10,000,000	5 Years	Yes (Budget)

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9

PCORI's Online Application System

NOTE

There are LOI template prescreen questions in the PCORI Online system.

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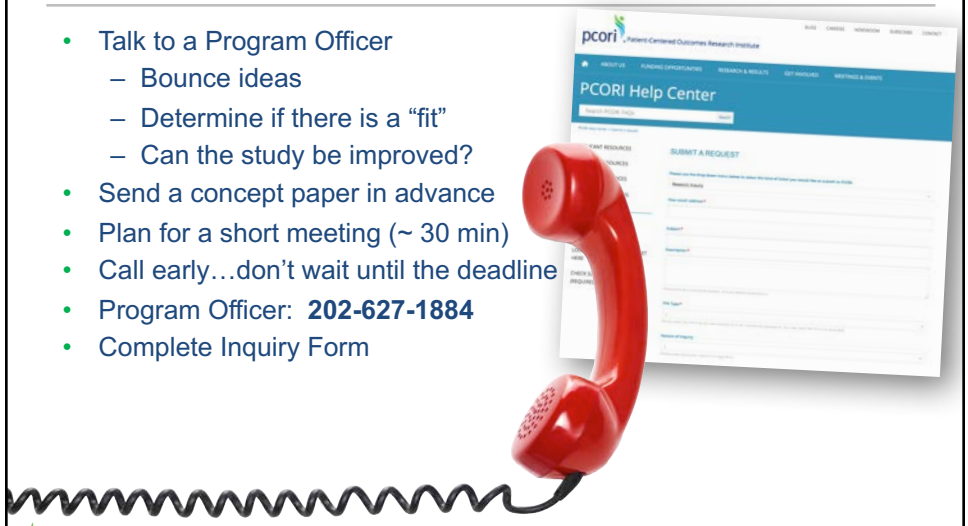
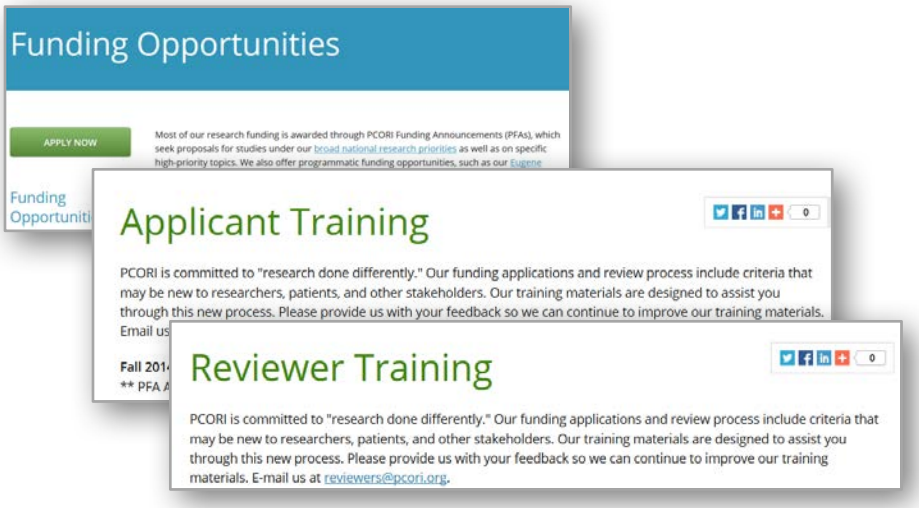
Let's Chat!

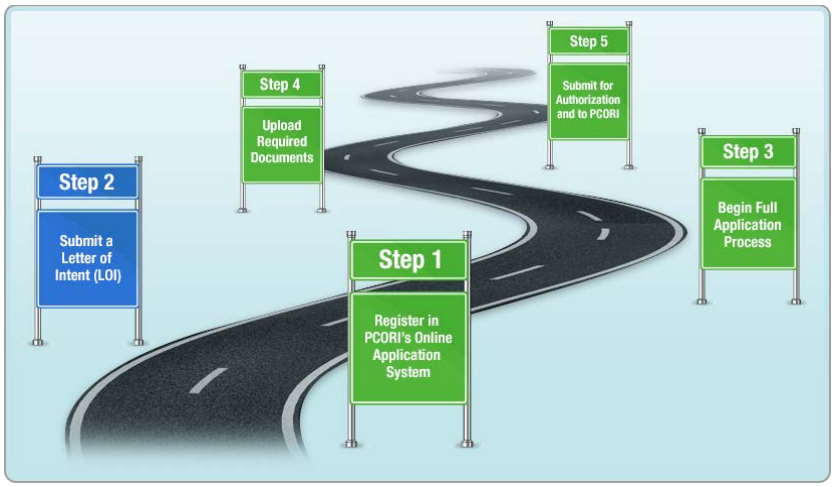
- Talk to a Program Officer
  - Bounce ideas
  - Determine if there is a "fit"
  - Can the study be improved?
- Send a concept paper in advance
- Plan for a short meeting (~ 30 min)
- Call early…don't wait until the deadline
- Program Officer: **202-627-1884**
- Complete Inquiry Form



Additional Resources

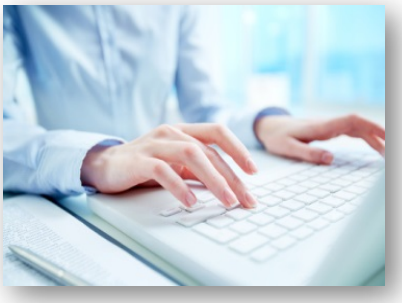


PCORI's Online Application Process



What is the Letter of Intent (LOI)?

- An LOI is required in order to submit an application
- LOIs are NOT scored
- The LOI includes:
  - Organizational Information
  - Information about Key Personnel
  - Technical Overview



NOTE

LOI is comprised of two components: **online questions** and an **uploaded file**.

What Does PCORI Want to See in an LOI? Video

Christopher Gayer, PhD, Program Officer, Communication and Dissemination Research
Patient-Centered Outcomes Research Institute
What we're looking for in a PCORI LOI, is first and foremost, a compelling decision dilemma. I think that the most compelling, comparative effectiveness research studies tend to start with a compelling real word decision dilemma, which is being faced by either a patient, a family member, a clinician, or another important stakeholder in healthcare. In these dilemmas, decision makers are faced with a choice between two or more options where there's uncertainty as to which of these choices is the best for that particular individual and in their particular situation.

Kara Odom Walker, MD, MPH, MSHS
Deputy Chief Science Officer
Patient-Centered Outcomes Research Institute
These options should be real decisional dilemmas that are faced by patients and clinicians. Describe what are the options? Why is it really compelling? And talk about why patients care about this particular decision.

We also hope that these comparators are used in real world settings and have documented efficacy data. We are not interested in funding pilot studies or other types of developmental work. If it's part of the larger project, that's acceptable, but we certainly want to have a true comparison that will help answer a question appropriate for clinical comparative effectiveness.

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15

Focus on "Filling the Gap"

- Examine the choices people make about the options for managing a disease
- Consider how compelling it is to make a choice among these options
- Assess the evidence about available options and their important outcomes
  - Systematic reviews
  - Evidence gaps that are important to decision makers
- Design a research project that compares the benefits and harms associated with each option

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16

PCORI's Two-Step LOI Review Process Video

Christopher Gayer, PhD
Program Officer, Communication and Dissemination Research
Patient-Centered Outcomes Research Institute

After you submit a letter of intent to PCORI, it goes through a process of two important steps. The first is an administrative review, to ensure that the LOI is compliant with the guidelines that are described in the funding announcement. At this stage, we're really looking to make sure that you adhered to the page limits and the formatting standards and that all of the requested content that we asked you to provide in the letter is in fact there.

Kimberly Bailey, MS
Program Officer, Clinical Effectiveness Research
Patient-Centered Outcomes Research Institute

After is goes through that administrative review, we go through a programmatic review. It's important to note that this programmatic review is not a scientific review at this point in time. That's what we do during our merit review process. The LOI review instead is seeking to determine whether your Letter of Intent adheres to what PCORI is seeking in the funding announcement that you're applying to. The Letter of Intent is reviewed by two or more PCORI staff, and during that review we are looking at things such as whether you've provided efficacy data, whether your post study includes a clear comparison, and other things to make sure its programmatically responsive. If your Letter of Intent is found to have a programmatically responsive question and comparators, you're invited to submit a full application with PCORI.

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17

Criterion 1. Potential for the Study to Fill Critical Gaps in Evidence

- Does the application convincingly describe the clinical burden?
- Does the application identify a critical gap in current knowledge as noted in systematic reviews, guideline development efforts, or previous research prioritizations?
- Does the application identify a critical gap in current knowledge evidenced by inconsistency in clinical practice and decision making?
- Would research findings from the study have the potential to fill these evidence gaps?

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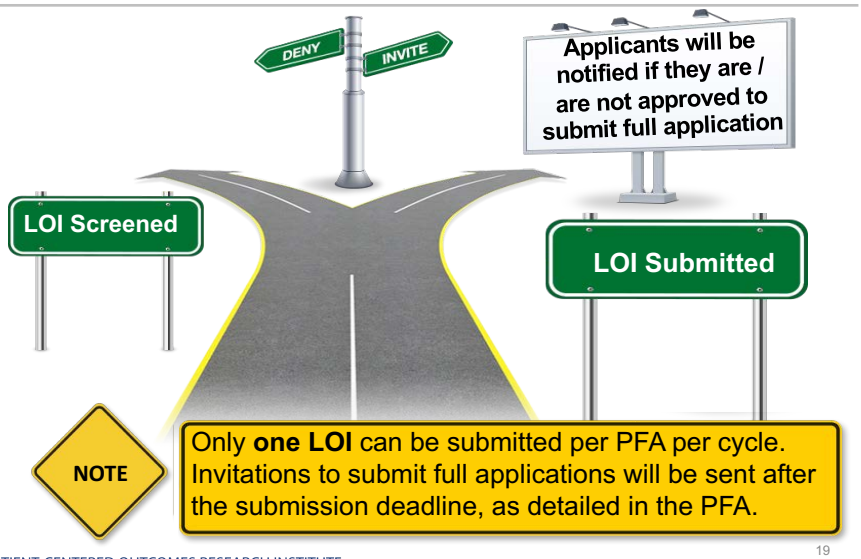
18

LOI Review and Approval Process



NOTE

Only **one LOI** can be submitted per PFA per cycle. Invitations to submit full applications will be sent after the submission deadline, as detailed in the PFA.

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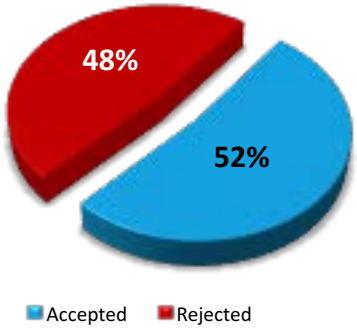
19

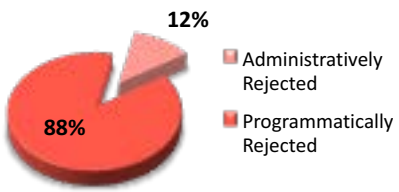
LOI Acceptance/Rejection

LOIs Received



LOIs received: 290
LOIs accepted: 152
LOIs rejected: 138

Reason for Rejection



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20

Reasons an LOI Can Be Rejected Video

Kara Odom Walker, MD, MPH, MSHS
Deputy Chief Science Officer
Patient-Centered Outcomes Research Institute
Some of the most common reasons that our LOIs are not invited for full application include a range of issues. Primarily we're reviewing for administrative non-compliance, but about seven percent of our LOIs are screened out for that reason. The other LOIs are often screened out for other reasons including not having sufficient data to support efficacy or not documenting the evidence gap through systematic reviews or clinical guidelines. We're also looking for a clear description of the comparators where the question is compelling and that there's data to suggest that will fill an evidence gap.

Christopher Gayer, PhD
Program Officer, Communication and Dissemination Research
Patient-Centered Outcomes Research Institute
Another big reason that the LOIs are not invited to submit a full application is because they are proposing to develop an intervention they want to study in their PCORI application. And so PCORI will not fund the development of new interventions from scratch as its really not consistent with the goal of comparative effectiveness research. Which is to compare two interventions that have already been developed, which have known efficacy or are in wide spread use. So often times folks will propose to develop their interventions in a Letter of Intent, which is a big no no at PCORI.

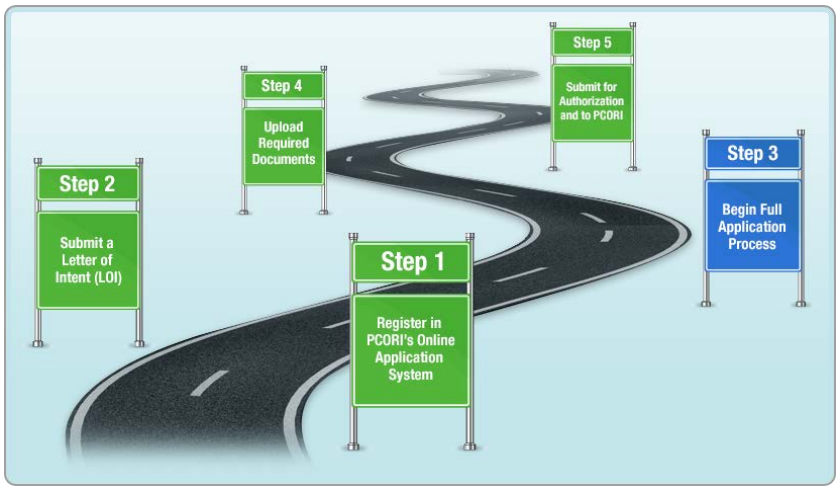
Tips for Success: Submitting a Responsive LOI Video

Kara Odom Walker, MD, MPH, MSHS
Deputy Chief Science Officer
Patient-Centered Outcomes Research Institute
My general tips for success are that you start early. We often announce the topical area before the funding announcement is even released. So we can tell when its rushed. Think about it and talk to your colleagues.

Christopher Gayer, PhD
Program Officer, Communication and Dissemination Research
Patient-Centered Outcomes Research Institute
It's also very important that you read the current funding announcement very closely before you submit a Letter of Intent in response to that announcement. The PFAs, the PCORI Funding Announcements, do change sometimes from cycle to cycle. So you want to make sure you're submitting to the PFA that's most current and not a PFA that is a year or even two years out of date.

Layla Lavasani, PhD, MHS
Program Officer, Clinical Effectiveness Research
Patient-Centered Outcomes Research Institute
I do suggest that you take a look at the website to better understand what we're already funding. To really ensure that your particular study idea is not currently funded.

PCORI's Online Application Process



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23

Planning for the Submission

- Create a calendar with all the key dates
  - Build buffers
  - Send materials for review early
- Download the full application package
  - Use the templates in the applicant resources
- Use an application checklist
  - List all the components
- Communicate often / Status Checks

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24

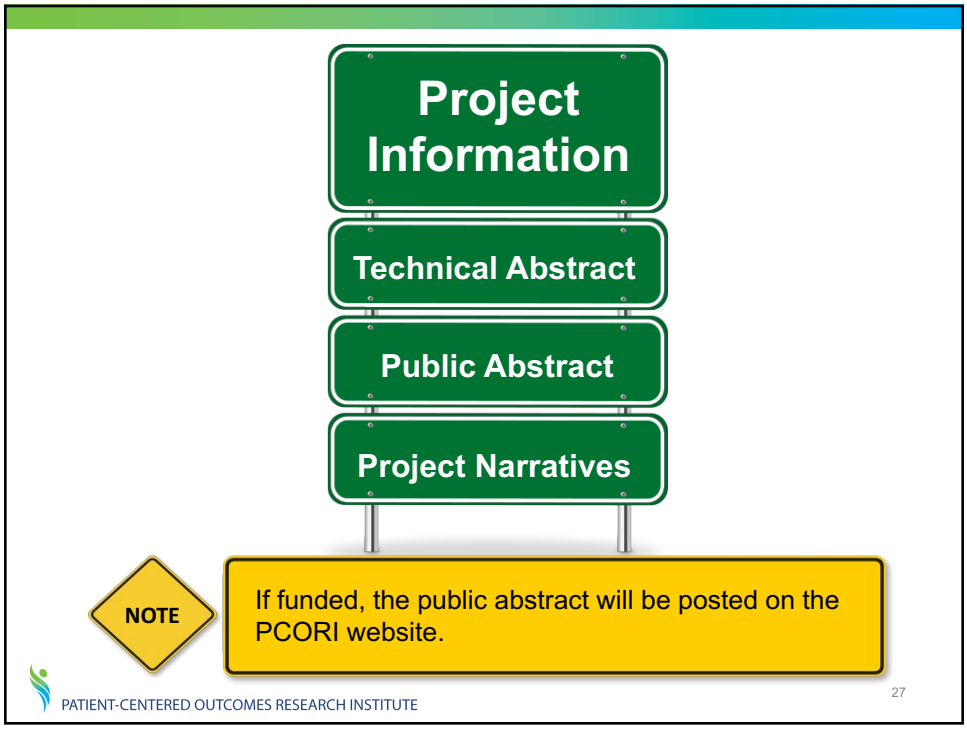
LOI to Application

You were invited to submit a full application based on the information provided in the LOI, changes after the LOI require PCORI approval.

Show stoppers include:

- Changes to the PI
- Changes to the Institution
- Changes to the Study Design
- Changes to Research Question
- Changes to Specific Aim
- Changes to Comparators

PCORI Online: Application



PCORI Monitors Projects Against Milestones & Deliverables

Milestones:
Significant events or accomplishments within the project; may have deliverables associated with them

Deliverables:
Measurable and verifiable outcomes or objects that a project team must create and deliver according to the contract terms

Milestone and Deliverable Schedule

Examples of milestones:

- When will you have IRB approval?
- When will enrollment begin?
- Key meetings
- 25% / 50% / 75% / 100% enrolled
- Completion of data analysis

Page Limit

3

Milestone/Deliverable Name	Milestone/Deliverable Description	Projected Completion Date
Year 1		

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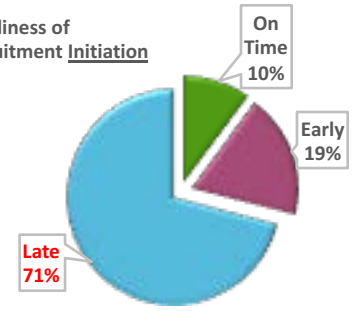
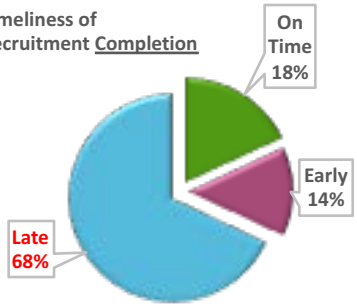
29

Patterns Among Studies that have Completed Recruitment

Timeliness of Recruitment Initiation



Timeliness of Recruitment Completion



- 57% Stay in same timeliness category
- 24% Start late but "Catch up"
- 19% Start on time but end late

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30

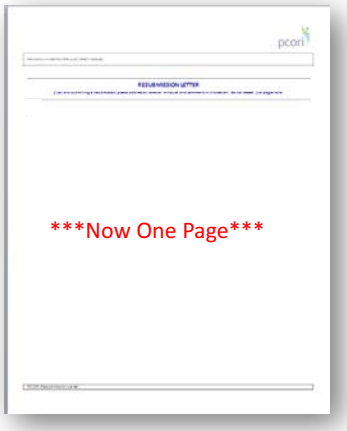
Resubmission Letter

What Constitutes a Resubmission?

- Same Topic, PFA
- Same PI
- Received Summary Statement

Notes on Resubmissions

- PCORI may invite PI's to resubmit
  - Not be reviewed with other LOIs
- PI's may choose to resubmit
  - Will undergo competitive LOI review
- Provide a high-level overview of how the application has been strengthened in its scientific merit and responsiveness to the current PFA
- Reviewed with other applications during merit review



Research Plan Template

Starting the Research Plan

Helpful Hints

- Demonstrate how the team you have will complete the project
- Describe your research approach and methods clearly
- Indicate how your project adheres to the Methodology Standards
- Ensure your research questions are comparative
- Use clear, concise language (avoid jargon)
- Review PCORI's Merit Review criteria in advance

Follow the page limits for each component of the Research Plan template.

Research Plan Template

Research Plan Template—Research Strategy

A. Background
B. Significance
C. Study Design or Approach
D. Patient Population
E. Research Team and Environment
F. Engagement Plan

Page Limit
20

Paint a Clear Picture for Reviewers and Staff

- What are the gaps in evidence?
- What is the impact of the condition?
- Why are the outcomes important to patients?
- How will the study improve the quality of evidence to make informed decisions?
- Describe the aims and research methods
- Describe the patient population, recruitment plan, and any barriers to enrollment
- How will you analyze the results?

Criterion 3. Scientific Merit

- Does the proposal describe a **clear conceptual framework** anchored in background literature which informs the design, key variables, and relationship between interventions and outcomes being tested?
- Does the application provide **justification that the outcome measures are validated** and appropriate for the population?
- Does the research plan describe rigorous methods that **demonstrate adherence to PCORI's Methodology Standards**?
- Are each of the **comparators clearly described and well justified**?
- Are the **sample sizes and power estimates based on careful evaluations** of the anticipated effect size?
- **Is the study plan feasible**?

Please see the PFA for the full description of this criteria.

A Strong Research Team Matters

- Is the PI the right fit?
  - Complexity of the project
  - Time commitments
  - Experience
- Have a complimentary team that offers different skills and perspectives
- Show / explain how the team will work together
- Include subject matter experts
- Novice and seasoned researchers benefit from mentorship

Organizational Capabilities

- Is there evidence of organizational commitment
  - Letters of support from Leadership
  - Departmental support
- Experience managing research
  - Mix of sponsors and size
  - Mix of types (e.g., grants vs. contracts)
- Central research office
  - Finance capabilities
  - Administration
  - Institutional Review Board
- Access to patients / participants
- Facilities
  - Medical facilities, computers, interview rooms, library
  - Specialties (e.g., radiology, pathology, nursing, social work)

Criterion 5. Patient-Centeredness

The application should demonstrate that the study focuses on improving patient-centered outcomes and employs a patient-centered research design (i.e., design is informed or endorsed by patients). The proposal should address the following:

- **Does the application include a thorough description about which outcomes (both benefits and harms) are important to patients, and are those outcomes included in the study plan?**
- Does the application provide information that indicates that closing the evidence gap is important to patients and other stakeholders?
- **Are the interventions being compared in the study available to patients now, and are they the best options for comparison** (including whether they would be chosen by patients and their healthcare providers for managing the condition being studied)?

Our Engagement Rubric–A Valuable Resource

Provides practical guidance to applicants, merit reviewers, awardees, and engagement/program officers on effective engagement in research

- **Planning the Study:** How patient and stakeholder partners will participate in study planning and design
- **Conducting the Study:** How patient and stakeholder partners will participate in the conduct of the study
- **Disseminating the Study Results:** How patient and stakeholder partners will be involved in plans to disseminate study findings and ensure that findings are communicated in understandable, usable ways

Consider PCOR Engagement Principles: Reciprocal relationships, co-learning, partnership, trust, transparency, honesty

Criterion 6. Patient and Stakeholder Engagement

- Does the application provide a well-justified description of how the research team is interdisciplinary? Does the study include the right individuals (researchers, patients, clinicians, other stakeholders) to ensure that the projects will be carried out successfully?
- **Does the application show evidence of active engagement among scientists, patients, and others throughout the entire research process** (e.g., formulating questions, identifying outcomes, monitoring study, dissemination, and implementation)? Is the frequency and level of patient and stakeholder involvement sufficient to support the study goals?
- Is the proposed engagement plan appropriate and tailored to the study?
- Are the roles and the decision-making authority of all study partners clearly described?
- Are the organizational structure and resources appropriate to carry out the project?

Dissemination and Implementation Potential

Page Limit
2

A. Describe the potential for disseminating and implementing the results of this research in other settings.

B. Describe possible barriers to disseminating and implementing the results of this research in other settings.

C. Describe how you will make study results available to study participants after you complete your analyses.

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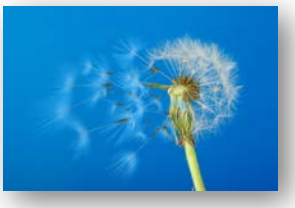
Definitions

- ***Dissemination*** is the…..
  - intentional, ***active*** process of identifying target audiences and tailoring communication strategies to increase awareness and understanding of evidence, and to motivate its use in policy, practice, and individual choices
  - The purpose of dissemination is to spread and sustain knowledge and the associated evidence-based interventions
  - ***Passive dissemination***, sometimes called research diffusion, is an untargeted dissemination process whereby new evidence is absorbed and acted upon by a small body of highly motivated recipients



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Definitions

- ***Implementation*** is the…..
  - deliberate, iterative process of integrating evidence into policy and practice through adapting evidence to different contexts and facilitating behavior change and decision making based on evidence across individuals, communities, and healthcare systems

Criterion 2. Adoption of Findings in Clinical Practice

- Does the application identify who will make the decision (i.e., the decision maker) or use (i.e., the end-user) the study findings (not the intervention) produced by this study, such as local and national stakeholders?
- Does the application identify potential end-users of study findings, such as local and national stakeholders, and describe strategies to engage these end-users?
- **Does the application provide information that supports a demand for this kind of a study from end-users?**
- Would research findings from this study have the potential to inform decision making for key stakeholders (provide example)? How likely is it that positive findings could be reproduced by others, resulting in improvements in practice and patient outcomes? Identify the potential barriers that could hinder adoption of the intervention by others.
- **Does the application describe a plan for how study findings will be disseminated beyond publication in peer review journals and national conferences?**

Protection of Human Subjects

- Describe the protection of human subjects involved in your research.

Page Limit
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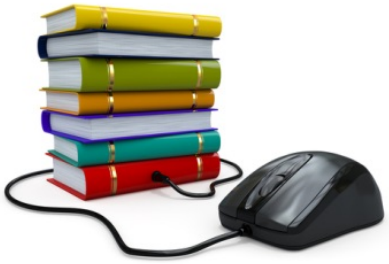
(each)

Consortium Contractual Arrangements

- Describe the proposed research projects that subcontracted organizations will perform.
- Explain the strengths that these partners bring to the overall project to ensure successful submission of contract deliverables in accordance with the milestone schedule.

References Cited

Follow scholarly citation practice and list the source material cited in your Research Plan.



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10

Appendix

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10

- PCORI applications may include an appendix for additional materials the investigators think may be useful, including:
  - Survey instruments
  - Papers and publications from members of the research team; however, **reviewers will not be required to include the appendices in the review and assessment of the project**

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51

People & Places Templates

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52

Criterion 4. Investigator(s) and Environment

NEW

- This criterion should assess the appropriateness (e.g., qualifications and experience) of the investigator(s)/team and the environment's capacity (e.g., resources, facilities, and equipment) to support the proposed project. It should not be an assessment of the institution's quality.
- The application should also address the following questions:
- How well-qualified are the PIs, collaborators, and other researchers to conduct the proposed activities? Is there evidence of sufficient clinical or statistical expertise (if applicable)?
- Does the investigator or co-investigator have demonstrated experience conducting projects of a similar size, scope, and complexity?
- If the project is collaborative or dual-PI, do the investigators have complementary and integrated expertise? Are the leadership, governance, and organizational structures appropriate for the project?
  - (Dual-PI Option Only) Does the Leadership Plan adequately describe and justify PI roles and areas of responsibility?
- Is the level of effort for each team member appropriate for successfully conducting the proposed work?
- Does the application describe adequate availability of and access to facilities and resources (including patient populations, samples, and collaborative arrangements) to carry out the proposed research?
- Is the institutional support appropriate for the proposed research?

When Proposing a Dual PI Application…

- One PI must be designated as the "Contact PI"
- The second PI is listed as the "Dual PI" within the PCORI Online System
- Only two PIs may be named
  - Can be from the same institution
  - Can be from another institution
  - Can have different focuses (e.g., engagement vs. scientific)
- Follow instructions when resubmitting an application with changes to the original dual PI team

Leadership Plan

Page Limit

5

- Describe the governance and organizational structure of the leadership team and the research project.
- Delineate the administrative, technical, scientific, and engagement responsibilities for each Principal Investigator (PI) and the rationale for submitting a dual-PI application.
- Discuss communication plans and the process for making decisions on scientific and engagement direction.
- Describe the procedure for resolving conflicts.

People and Places Template

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5

per person

Biosketch

- Professional Profile/Biosketches are required for **all key personnel.**
- You may use the National Institutes of Health (NIH) biosketch or PCORI's format.
- List all partners within the Key Personnel section.
- Patient and stakeholder partners may choose to complete the Patient and Stakeholder Partner Profile/Biosketch form.

Project/Performance Site

- Demonstrate that the proposed facilities have the appropriate resources required to conduct the project as planned, within budget, and on time.
- Provide a description of the facilities that will be used during the project, including capacity, capability, characteristics, proximity, and extent of availability to the project.

Page Limit
15

NOTE

Follow PCORI's required naming conventions when uploading PDF files!

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57

Budget

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58

Embrace Your Inner Accountant

Follow these three points and you should be fine with most funders:

- **Be realistic**
  - Do you really need the maximum allowable budget?
  - Avoid the danger of wanting to stretch every penny
- **Be detailed**
  - Breakout the costs by category
  - Include quotes / estimates
- **Justify your costs**
  - Explain what funds will be used for
  - Tie the costs to the scope of work
  - Note any abnormal requests

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59

Allowable and Unallowable Costs

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60

Frequently Rejected Costs

- DATA PLANS (TABLETS AND OTHER MOBILE DEVICES)
- DOCKING STATIONS
- DOUBLE MONITORS
- ELECTRONICS PROTECTION PLANS
- OFFICE FURNITURE
- REPLACEMENT OF ITEMS PURCHASED ON AN EXISTING PCORI AWARD

Indirect Costs

- Indirect costs are calculated at up to 40% of the allowable direct costs
- If you do not have an audited indirect cost, you may request up to 10% indirect costs
  - Must be noted in the Budget Justification
- Foreign organizations may request up to 10% indirect costs
- You may assess indirect costs on the first $25,000 of each subcontractor NEW

Letters of Support

Letters of Support

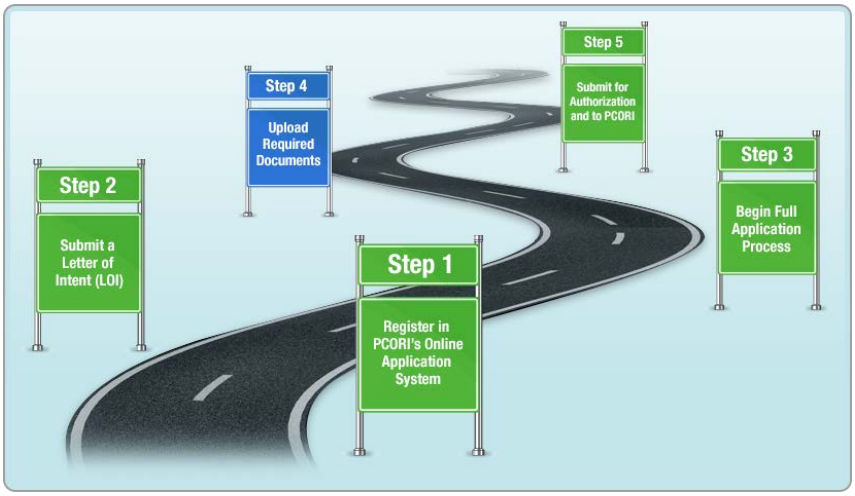
Purpose

Demonstrate the commitment of key personnel and/or your organization's leadership to the research project

Helpful Hints

- Address letters to the PI
- Not required for research assistants or others who are not contributing in a substantive, measurable way to the project
- Letters from your leadership and/or organizations supporting dissemination and implementation of research findings are strongly encouraged
- Follow instructions, a Letters of Support table has been added

PCORI's Online Application Process



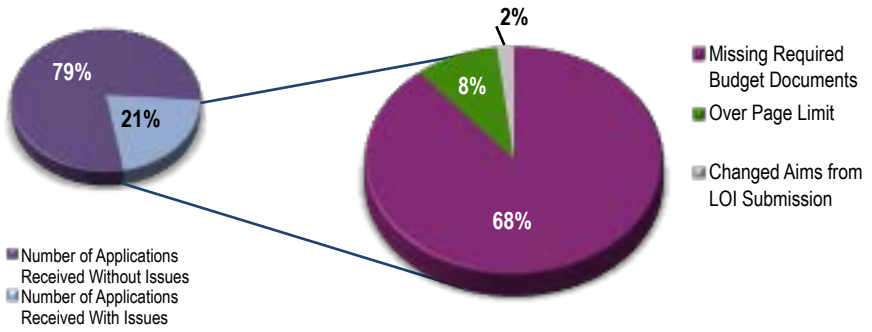
Administrative Requirements

- Include but are not limited to:
  - Required Templates
  - Length/Limit
  - File Formats
  - Font and Margin Sizes

NOTE

Applications that **do not meet the formatting criteria** or documentation requirements may be reduced to the page limit..

Why Checklists Matter



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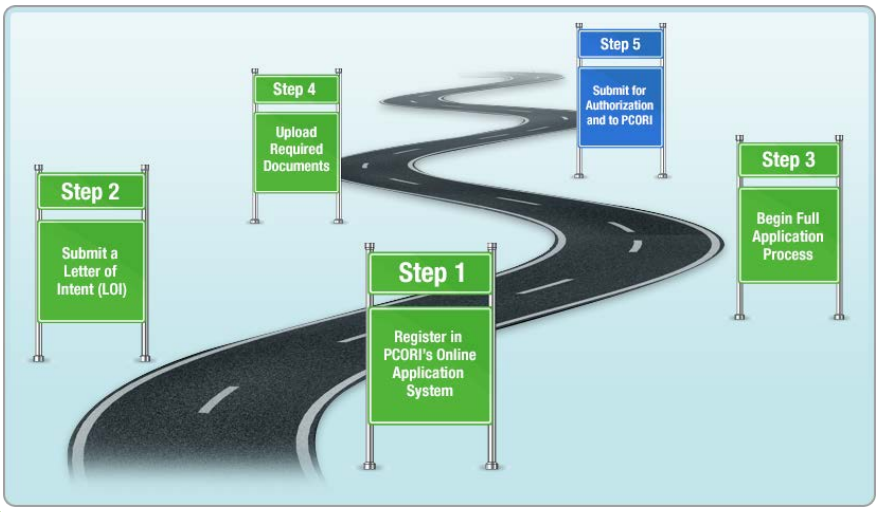
67

PCORI's Online Application Process



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68

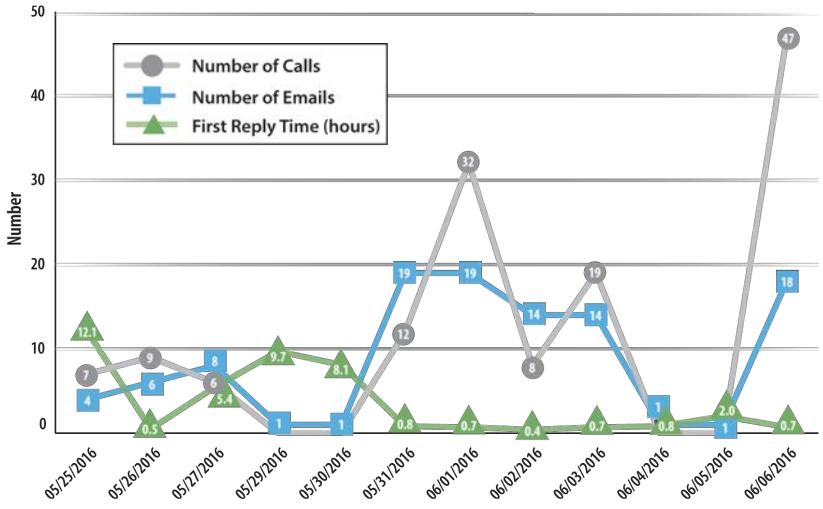
Tips for Success

- Adhere to the PFA and Application Guidelines for the **funding cycle you are applying to**
- Talk to a Program Officer if you have questions
- Start and submit early
- Download PCORI's Online User Manual for Submitting an Online Application
- Ensure that all team members can see the application in the system (check during the LOI stage)
- Inform your AO of your intent to submit
- Submit the completed application before the due date or on it by **5:00 PM ET**

PCORI Help Center

Program Officer: 202-627-1884
Helpdesk (8:30–5:00 EST): 202-627-1885 pfa@pcori.org

Helpdesk at Close of Cycle



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71

What Happens Next?
PCORI's Merit Review Process

~5 Months

Application Deadline → **Final Decision**

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Building an Inclusive Merit Review

- Panels include scientists, patients, and other stakeholders to bring diverse perspectives to the review process.
- Each application is assigned to 3 scientists, 1 patient, and 1 other stakeholder.
- Chair facilitates discussion and promotes a culture of mutual respect and understanding among reviewer types.

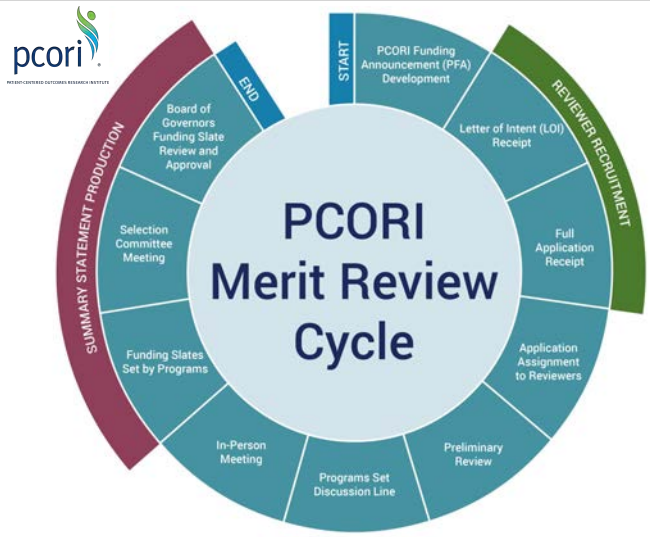
Scoring Range

A score of 1 indicates an exceptionally strong application.

Range	Score	Descriptor	Characteristics
High	1	Exceptional	Exceptionally strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor weaknesses
Medium	4	Very Good	Strong but with numerous minor weaknesses
	5	Good	Strong but with at least one moderate weakness
	6	Satisfactory	Some strengths but also some moderate weakness
Low	7	Fair	Some strengths but with at least one major weakness
	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and numerous major weaknesses

A score of 9 indicates an application with serious and substantive weaknesses.

Merit Review



Summary Statements

- All applicants receive a summary statement at the end of the review cycle.

If the application is discussed, summary statement includes:

- Preliminary reviewer critiques
- Notes from application discussion
- Final panel average overall score

If the application is not discussed, summary statement includes:

- Preliminary reviewer critiques

PCORI Information Request (PIR)

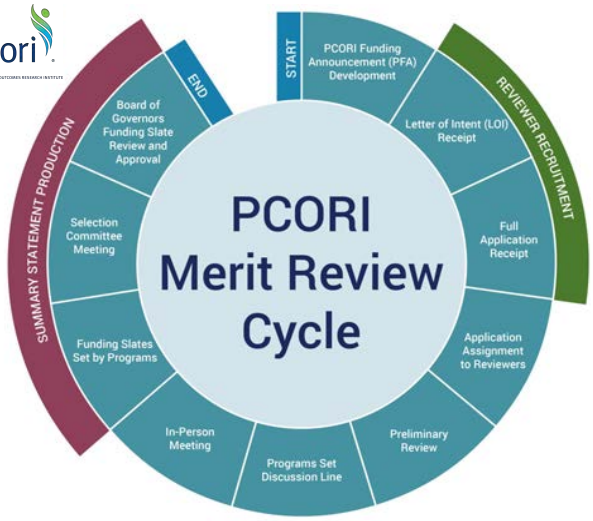
- A formal instrument for PCORI to request additional information or clarify issues/concerns raised during the review process.
- The PIR letter may ask applicants to address both administrative and programmatic issues.
- Applicant responses to the PIR request may be used by PCORI staff to help develop a funding slate.
- Applicants typically have 1–2 weeks to respond to the request letter.
- **Receipt of a PIR letter should not be construed as an intent to fund by PCORI.**
- **Applicants may be required to submit verification of their current, pending or other support.**

Post-Panel Review

- PCORI program staff:
  - Evaluate final merit review panel scores/comments.
  - Identify duplication or synergy among funded projects.
  - Consider the fit of applications within the programmatic vision.
- The Selection Committee:
  - Takes PCORI program staff recommendations and identifies a slate of applications for possible funding based on:
    - Merit review scores
    - Programmatic balance and fit
    - PCORI's strategic priorities

PCORI will not award new contracts to current awardees with overdue reports (progress, interim, final, etc.) until the overdue reports have been submitted to PCORI.

Merit Review



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79

Questions?

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Thank You!

James Hulbert, Assistant Director, Policy and Planning
Contracts Management and Administration

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