

The PCORI Application Process

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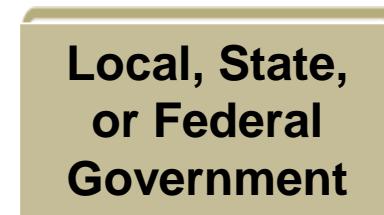
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Application Requirements: Who Can Apply?

- Any private sector research organization



- Any public sector research organization



- Foreign Organizations
- Nondomestic Components of Organizations based in US



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



PCORI's Online Application Process



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 2015	AD	10/12/15	11/12/15	2/16/16	May 2016	July 2016
	APDTO					
	CDR					
	IHS					
	PCS					
	Methods					
Cycle 1 2016	AD	2/1/16	March 2, 2016	June 6, 2016	September 2016	November 2016
	APDTO					
	CDR					
	IHS					
	Methods					
Cycle 2 2016	PCS	4/4/16	May 4, 2016	August 8, 2016	November 2016	January 2017



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 (<i>large</i>)	5 Years	No
		\$1,500,000 (<i>small</i>)	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 Million	\$10,000,000	5 Years	Yes (Budget)



Greater than Budget Request

Please refer to PFA on instructions on how to submit a Greater Than Budget Request.

Justify...Justify...Justify



PCORI's Online Application System

The screenshot shows the PCORI Online Application System login page. On the left, there is a sidebar with fields for 'Login Name', 'Username', 'Password', and 'Sign in'. Below these are links for 'Forgot your password?' and 'Reset password'. On the right, there is a large green rectangular overlay with the text 'Come visit the Help Desk while you are here!' in white and blue. Below this, in smaller text, is 'or' and 'PCORI new create'. At the bottom of the green box, there is a note: 'password" link to the left to receive your new password.' The overall background of the page is white with some faint text and icons.

NOTE

There are new LOI Template prescreen questions in the PCORI online system.



PCORI's Online Application Process



What is the Letter of Intent (LOI)?

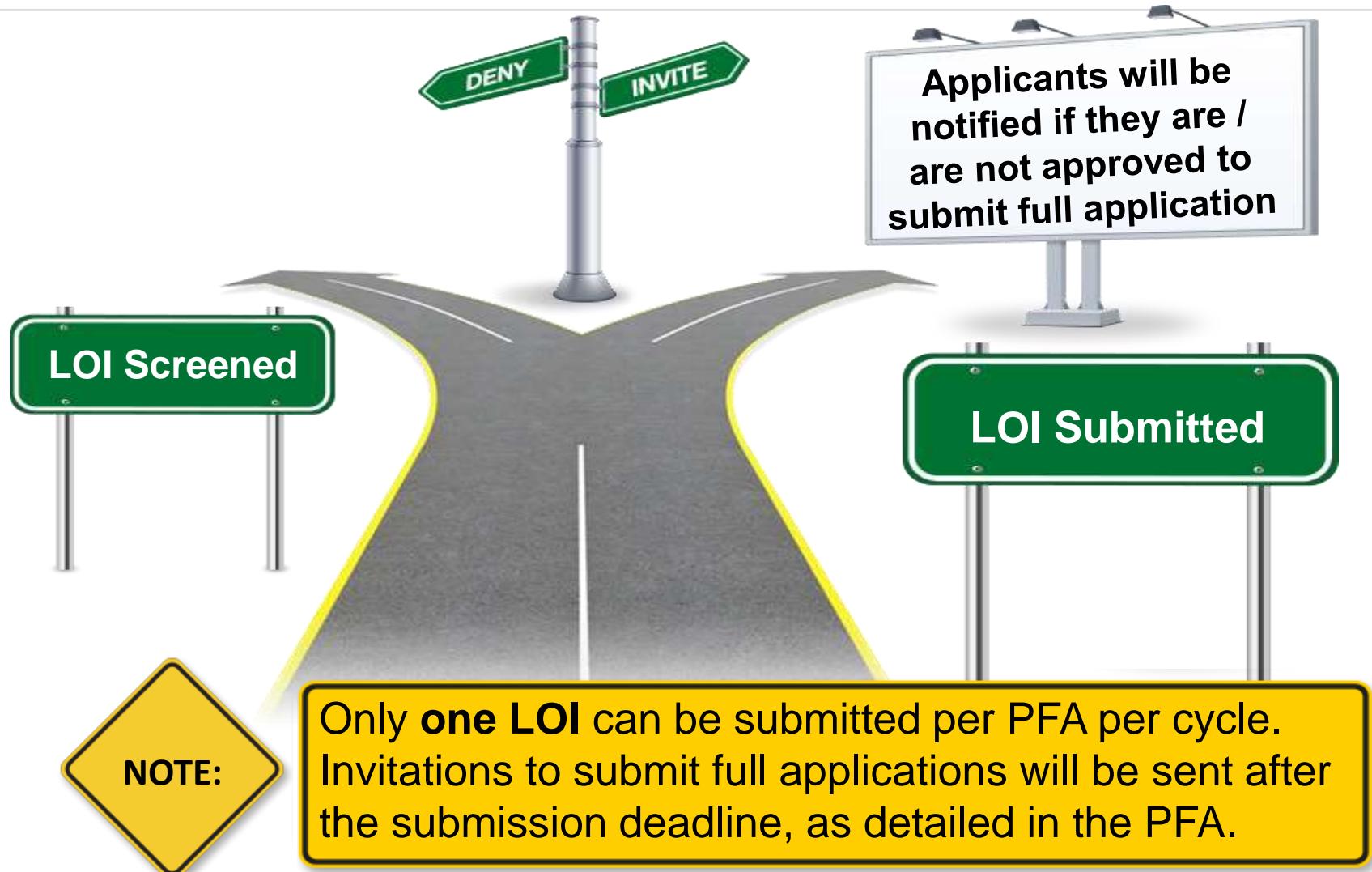
- An LOI is required in order to submit an application
- LOIs are NOT scored
- The LOI includes:
 - Organizational Information
 - Information about Key Personnel
 - Technical Overview



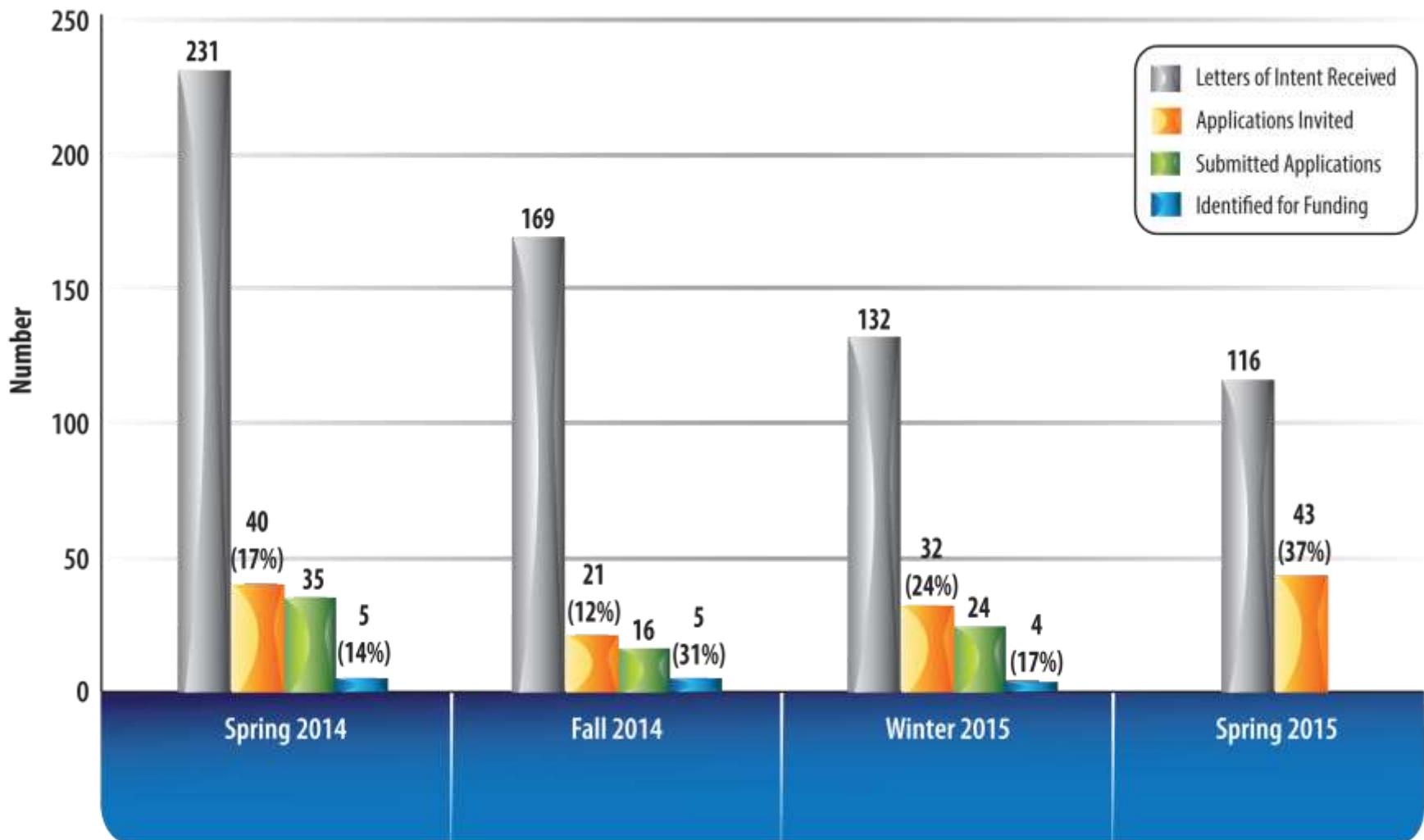
LOI is comprised of two components: **online questions** and an **uploaded file**.



LOI Review and Approval Process



LOIs, Applications, and Awards: First 4 Cycles of Pragmatic Clinical Studies



PCORI's Online Application Process



PCORI Online: Application

- PI and Contact Information
- Project Information
- Key Personnel
- Milestones
- Templates and Uploads
- Save and Review



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



Project Information

Technical Abstract

Public Abstract

Project Narratives

NOTE

If funded, the public abstract will be posted on the PCORI website.



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

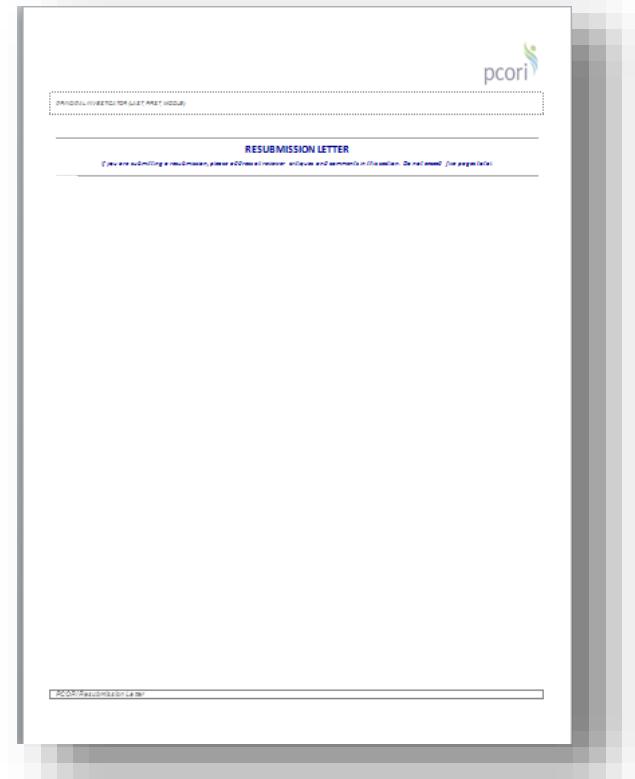


Resubmission Letter



Resubmission Letter

- Review and address the previous reviewers' comments thoroughly
- No limit



NOTE

Information regarding resubmissions has been updated in the Resubmission Letter section.



What Constitutes a Resubmission?

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



Research Plan Template



Research Plan Template: Overview



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

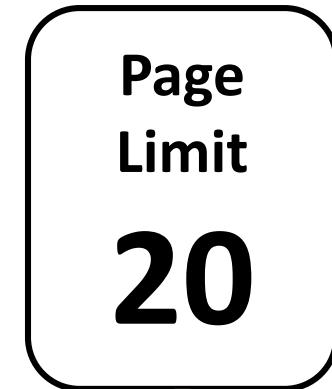
NOTE:

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



Research Plan Template—Research Strategy

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



- 1. New tables added in Sections D and E.
- 2. Updated Engagement Rubric.

Dissemination & Implementation

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.



Replication & Reproducibility of Research and Data Sharing

- A. Describe the ability to reproduce potentially important findings from this research in other data sets and populations.
- B. Describe how you will make a complete, cleaned, de-identified copy of the final data set used in conducting the final analyses available within 90 days of the end of the final year of funding, or your data-sharing plan, including the method by which you will make this data set available, if requested.
- C. Propose a budget to cover costs of your data-sharing plan, if requested.

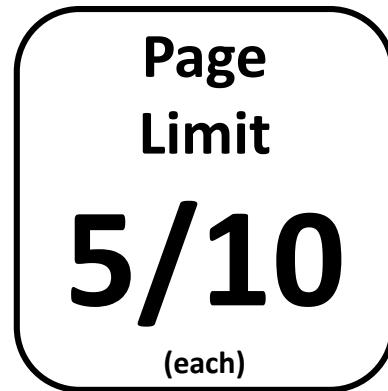
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2



Protection of Human Subjects

- Describe the protection of human subjects who will be involved in your research



Consortium Contractual Arrangements

- Describe the proposed research projects that will be performed by subcontracted organizations; explain the strengths that these partners bring to the overall project



References Cited

Following scholarly citation practice, list the source material cited in this Research Plan



Page
Limit
10



Appendix

Page
Limit

10

- PCORI applications may include an appendix for additional materials the investigators think may be useful
 - 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



People & Places Templates



People and Places Template



Biosketch

- You may use the NIH biosketch or PCORI's format
- Biosketches are required for all key personnel
- List all partners within the Key Personnel section
- Patient/Stakeholder Biosketch

**Page
Limit**

5

Per person

NOTE:

New page limit: Biosketches may now be 5 Pages per person.



People and Places Template

Project/Performance Site

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

**Page
Limit
15**



Budget



Budget

- Be reasonable
- Be detailed
- Justify your costs



Allowable and Unallowable Costs

Allowable Costs							
 PERSONNEL SALARIES & BENEFITS	 TRAVEL COST	 SUBCONTRACTOR DIRECT & INDIRECT	 APPLICANT INDIRECT COSTS				
 CONSULTANT FEES	 EQUIPMENT	 SUPPLIES	 OTHER				
Commonly Disallowed Costs							
 DATA PLANS (TABLETS AND OTHER MOBILE DEVICES)	 ADVERTISING	 DONATIONS	 INTEREST OF BAD DEBTS				
 DOCKING STATIONS	 EXCESSIVE AIRFARE	 FUNDRAISING	 ENTERTAINMENT				
 DOUBLE MONITORS	 ALCOHOLIC BEVERAGES	 PERSONAL EXPENSES	 LOSSES ON OTHER GRANTS				
 ELECTRONICS PROTECTION PLANS	 ALUMNI ACTIVITIES	 STUDENT HOUSING AND STIPENDS	 MEMBERSHIPS				
 OFFICE FURNITURE	 BAD DEBTS/LOSSES	 IDLE FACILITIES	 LOBBYING				
 REPLACEMENT OF ITEMS PURCHASED ON AN EXISTING PCORI AWARD			 RENT				
Unallowable Costs							

NOTE

Review Appendix 3 of Application Guidelines for updates on allowability of patient and clinical care costs.

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 only assess indirect costs on the first \$25,000 of all consortium/subcontractor costs combined



40%

NOTE:

New Requirement: the use of 10 percent indirect cost rate must be noted in the Budget Justification.



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



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



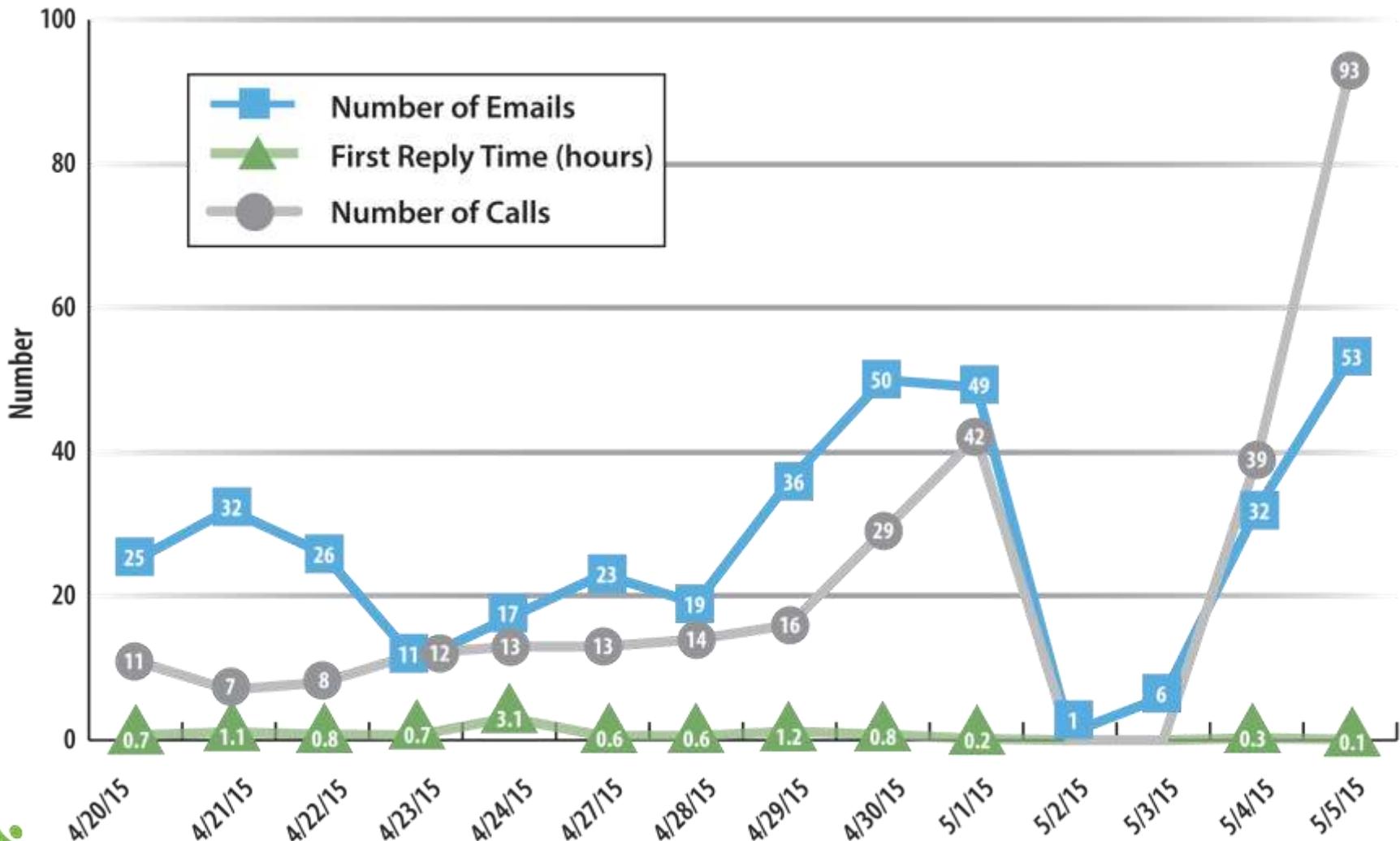
The screenshot shows the PCORI Help Center homepage. At the top, there is a navigation bar with links to 'ABOUT US', 'FUNDING OPPORTUNITIES', 'RESEARCH & RESULTS', 'GET INVOLVED', and 'MEETINGS & EVENTS'. Below the navigation bar, the title 'PCORI Help Center' is displayed. To the right of the title is a search bar with the placeholder 'Find Help Center answers' and a 'Search' button. On the left side of the main content area, there are three categories: 'APPLICANT RESOURCES', 'REVIEWER RESOURCES', and 'ENGAGEMENT AWARDS'. Below these categories is a horizontal line. Underneath the line are two buttons: 'ASK A QUESTION' and 'CHECK EXISTING QUESTIONS'. To the right of the categories, there is a section titled 'Applicant Resources' with a sub-section description: 'Applying to PCORI? Please review information in this section if you are submitting a letter of intent, full application, or if you have already applied for funding.' Below this text is a photograph of a woman with blonde hair, smiling, sitting at a table with other people.

Program Officer: 202-627-1884

Help Desk (8:30-5:00 EST): 202-627-1885 pfa@pcori.org



Help Desk at Close of Cycle



Additional Resources

Funding Opportunities

APPLY NOW

Most of our research funding is awarded through PCORI Funding Announcements (PFAs), which seek proposals for studies under our [broad national research priorities](#) as well as on specific high-priority topics. We also offer programmatic funding opportunities, such as our [Eugene](#)

Funding Opportunities

Applicant Training



PCORI is committed to "research done differently." Our funding applications and review process include criteria that may be new to researchers, patients, and other stakeholders. Our training materials are designed to assist you through this new process. Please provide us with your feedback so we can continue to improve our training materials.

Email us

Fall 2014
** PFA A

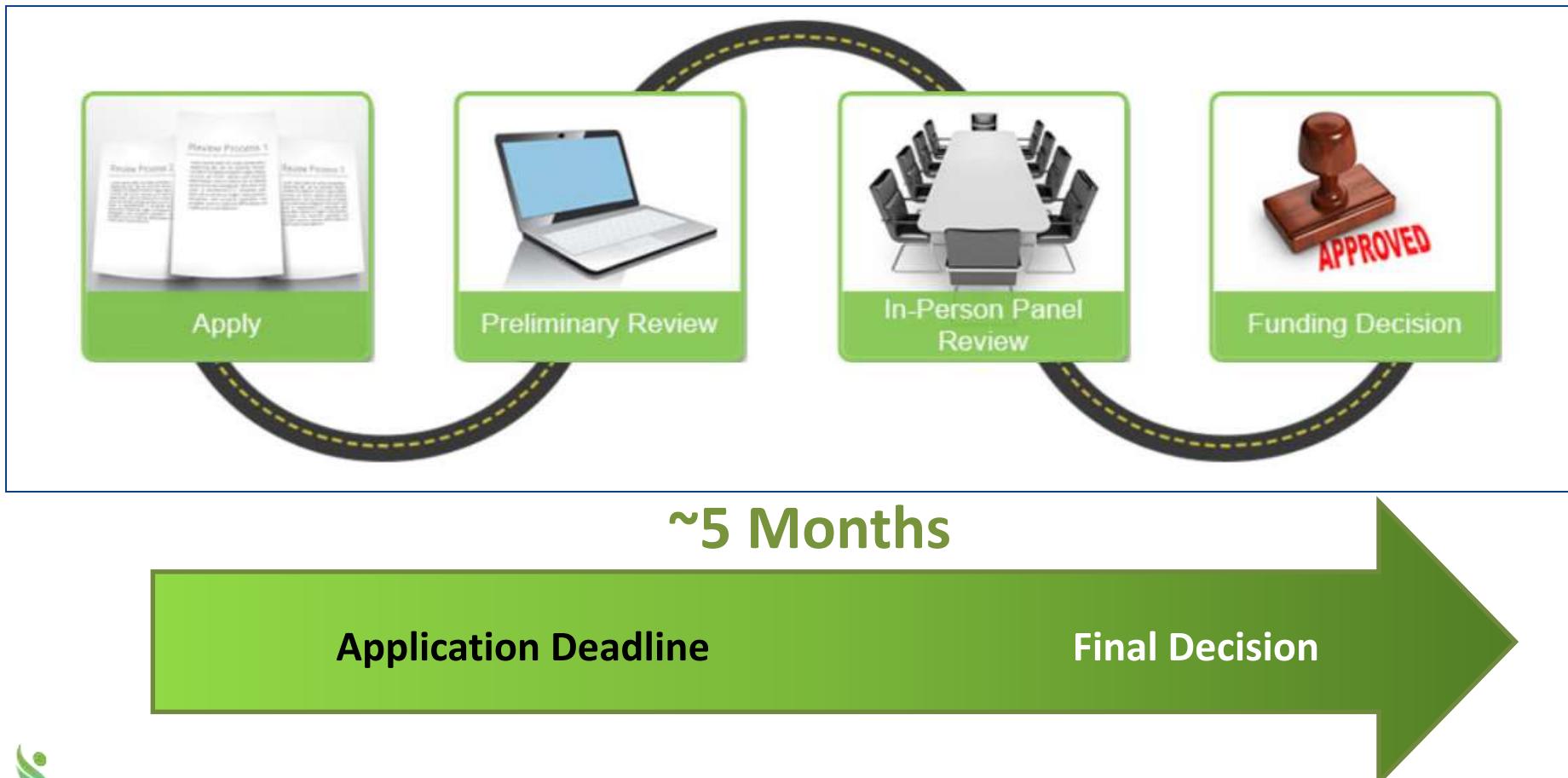
Reviewer Training



PCORI is committed to "research done differently." Our funding applications and review process include criteria that may be new to researchers, patients, and other stakeholders. Our training materials are designed to assist you through this new process. Please provide us with your feedback so we can continue to improve our training materials. E-mail us at reviewers@pcori.org.



What Happens Next? PCORI's Merit Review Process



Administrative Screening

Applicants **must follow** administrative requirements set in PCORI's Application Guidelines.



- ▶ Exceeding page limits, budget, or time limitations
- ▶ Not using PCORI's required templates
- ▶ Submitting incomplete sections or applications
- ▶ Modifying margins or font size



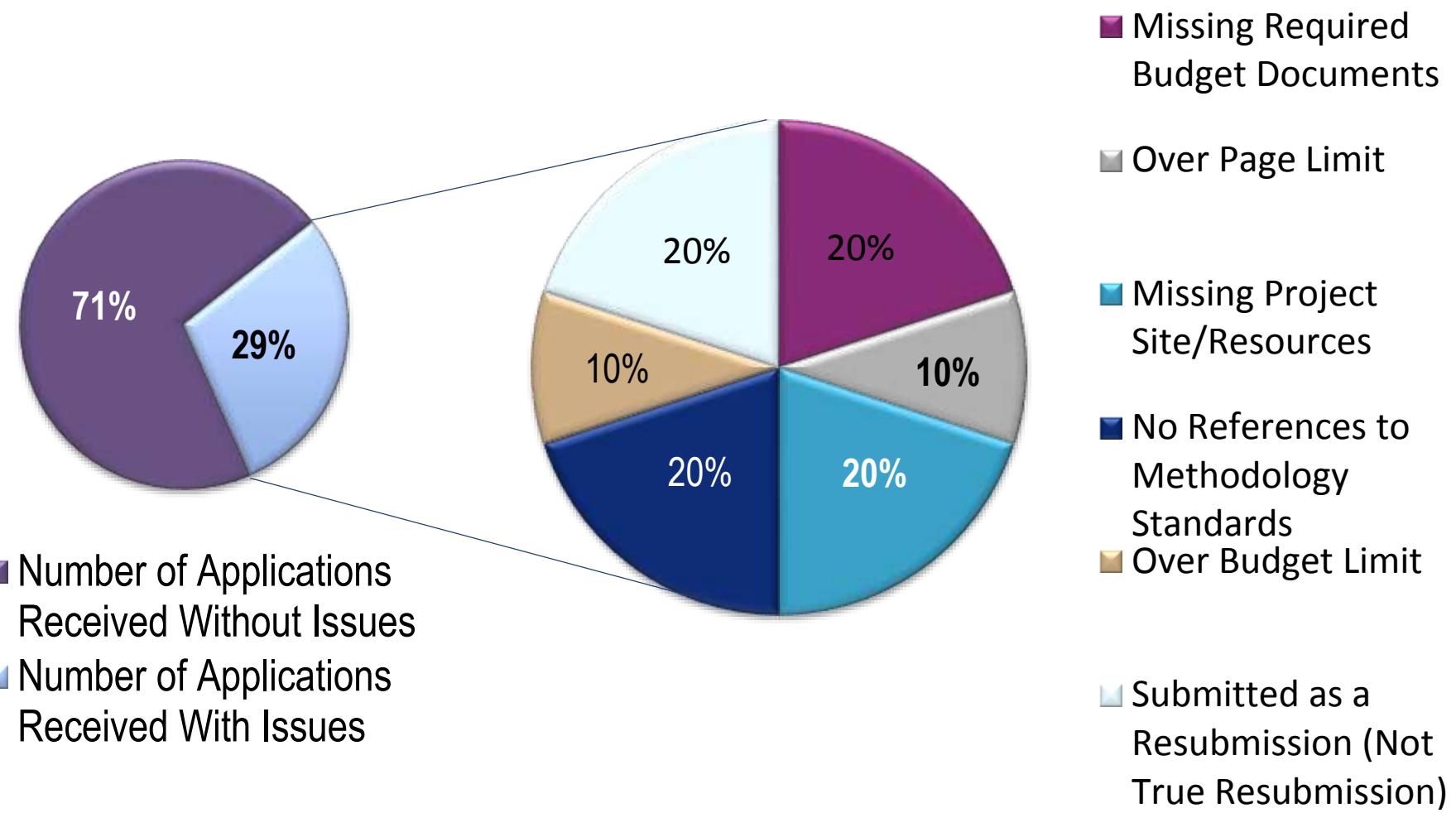
Programmatic Screening



- ▶ Study deviates from approved LOI
- ▶ Study includes cost-effectiveness analysis
- ▶ Study is not responsive to PFA and/or does NOT address the PFA's "Research Areas of Interest"
- ▶ Study is not comparative



Applications Screening Statistics



Merit Review



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



Patients



Other Stakeholders



Scientists



Merit Review Criteria

Patient and Other Stakeholder Reviewers	Scientist Reviewers
 Criterion #1: Impact of the condition on the health of individuals and population	✓
 Criterion #2: Potential for the study to improve healthcare and outcomes	✓
 Criterion #3: Technical merit	✓
 Criterion #4: Patient-centeredness	✓
 Criterion #5: Patient and other stakeholder engagement	✓



Scoring Range

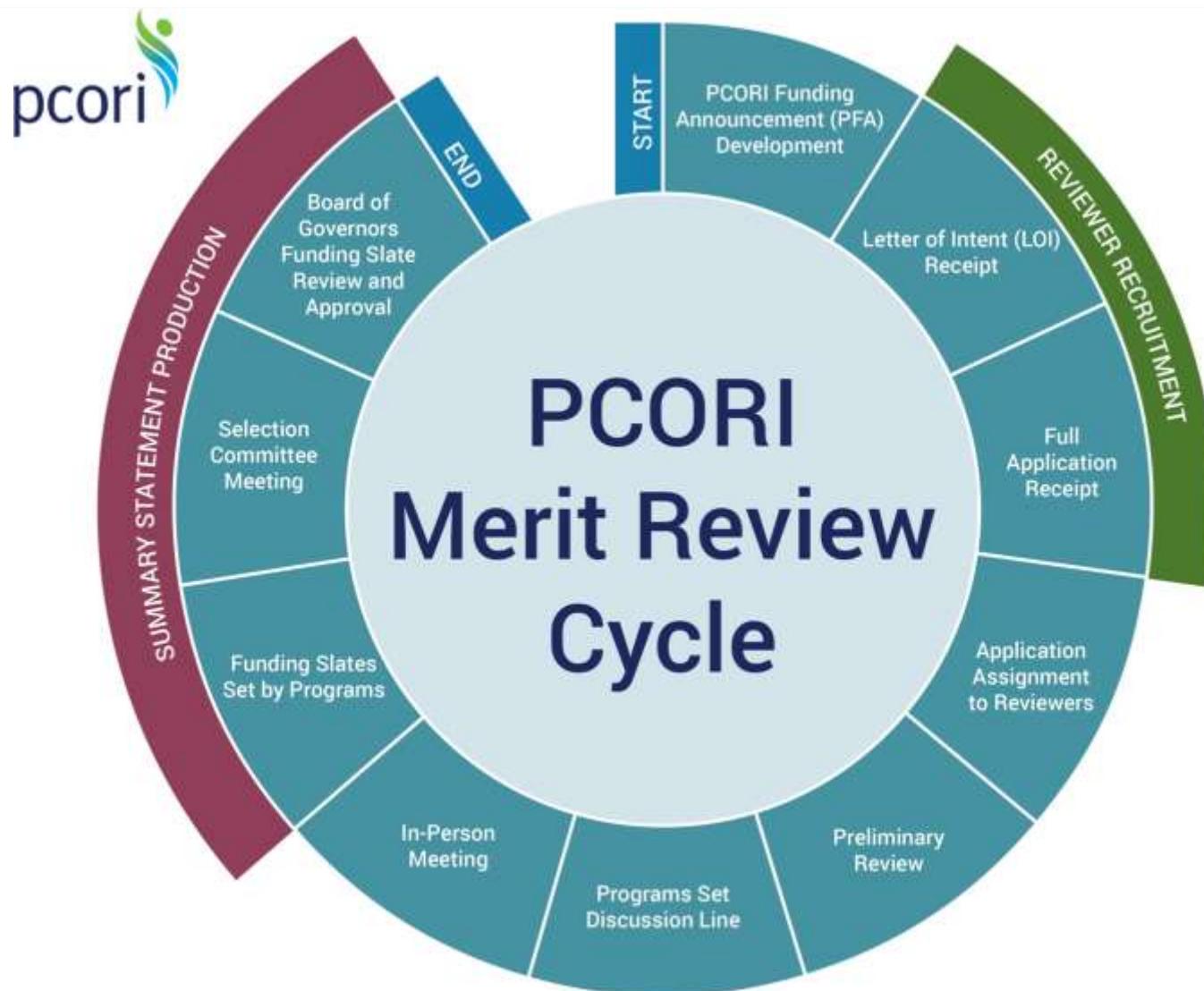
A score of 1 indicates an exceptionally strong application.

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.**



Questions?