

The PCORI Application Process

James Hulbert, Iris Giggetts, and Mary Gardner

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Welcome!



James Hulbert
Pre-Award Manager



**Iris Giggetts,
MSW, CRA**
Contracts Associate,
Pre-Award



Mary Gardner, CRA
Contracts Associate,
Pre-Award



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In This Session

- List and define each section of the PCORI application
- State the purpose of each template in the PCORI Application Process
- Submit an online application without errors
- Discuss the PCORI information request process
- Describe the Merit Review Cycle



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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



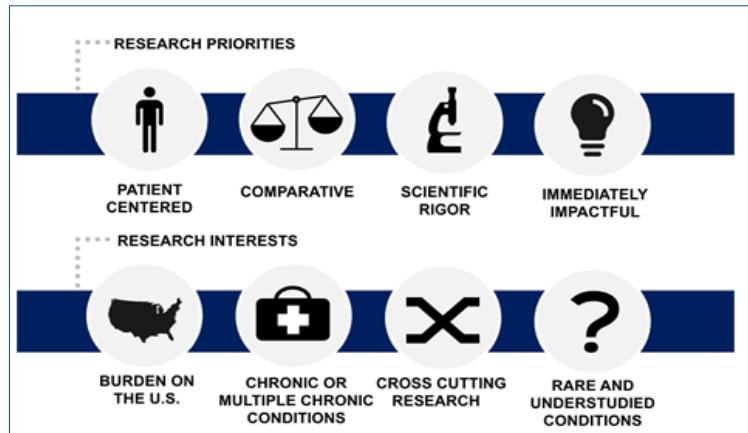
PI must be an employee of the prime applicant institution. Individuals are not eligible to submit research applications to PCORI.



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What Does PCORI Look For in Applications?



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PCORI's Online Application Process



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The PCORI Funding Center

pcori Patient-Centered Outcomes Research Institute

BLOG CAREERS NEWSROOM SUBSCRIBE CONTACT

ABOUT US FUNDING OPPORTUNITIES RESEARCH & RESULTS GET INVOLVED MEETINGS & EVENTS

Search

Funding Opportunities

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.

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Upcoming Funding Opportunities

Cycle	Funding Opportunity	PCORI Online Opens	LOI Due	Full Application Due	Merit Review Meeting	Awards Announced
Cycle 2 2015	AD	6/29/15	7/29/15	11/3/15	February 2016	April 2016
	APDTO					
	CDR					
	IHS					
	Methods					
Cycle 3 2015	AD	10/12/15	11/12/15	2/16/16	May 2016	July 2016
	APDTO					
	CDR					
	IHS					
	PCS					
	Methods					

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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)



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Greater than Budget/Time Request: Budget Limitations

Please refer to PFA on instructions on how to submit a Greater Than Budget and/or Time Requests.



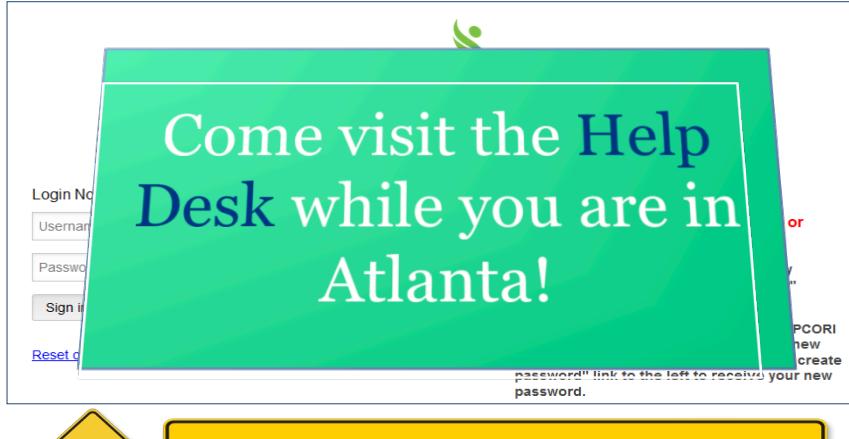
Justify...Justify...Justify



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PCORI's Online Application System



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PCORI's Online Application Process



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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**.



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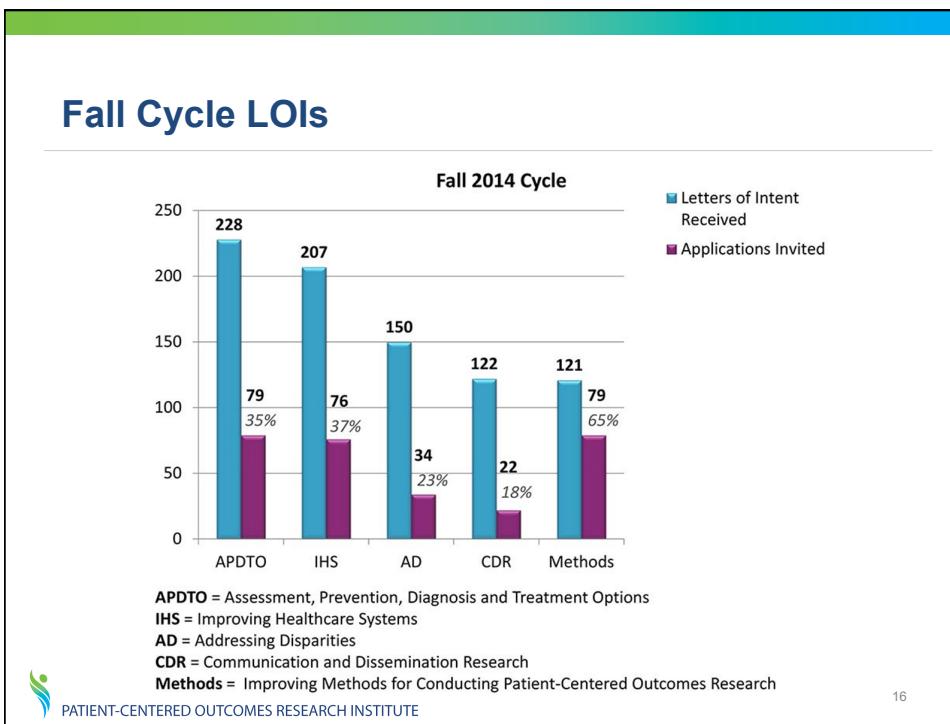
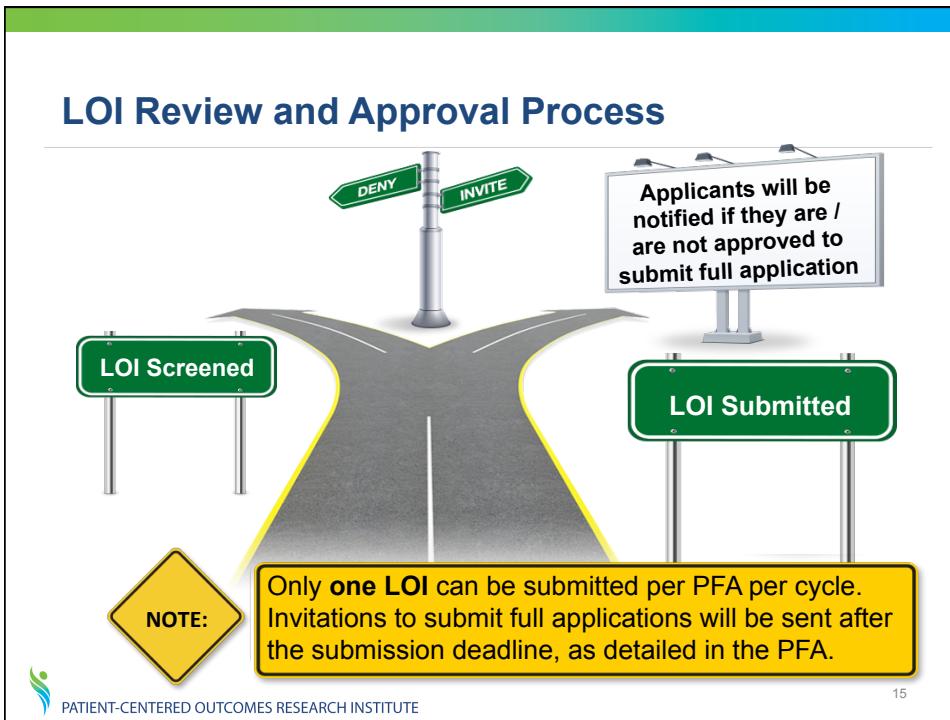
Responsiveness Review

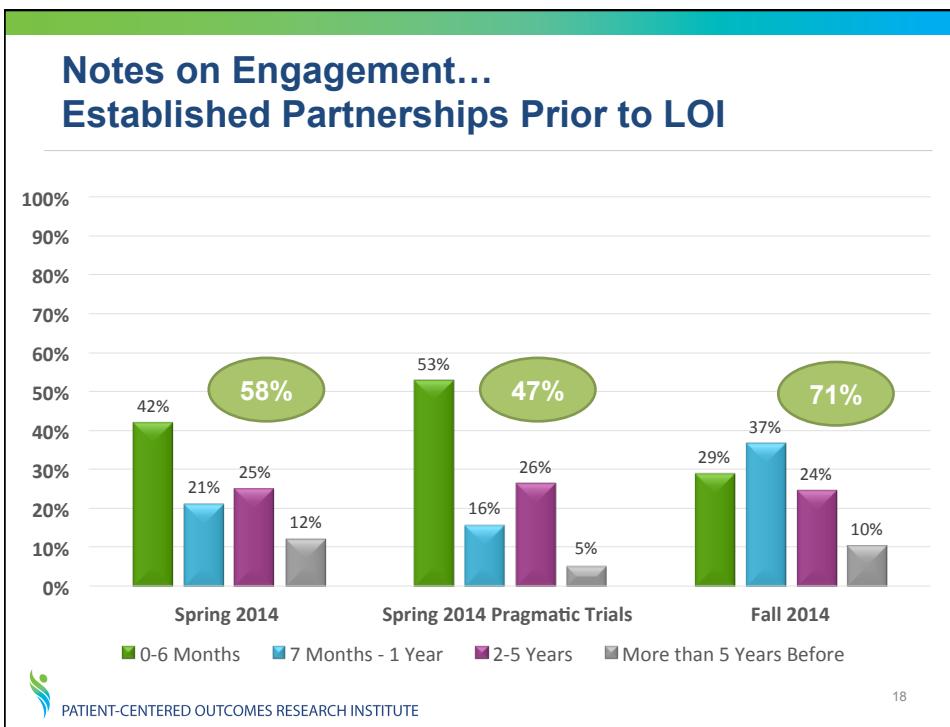
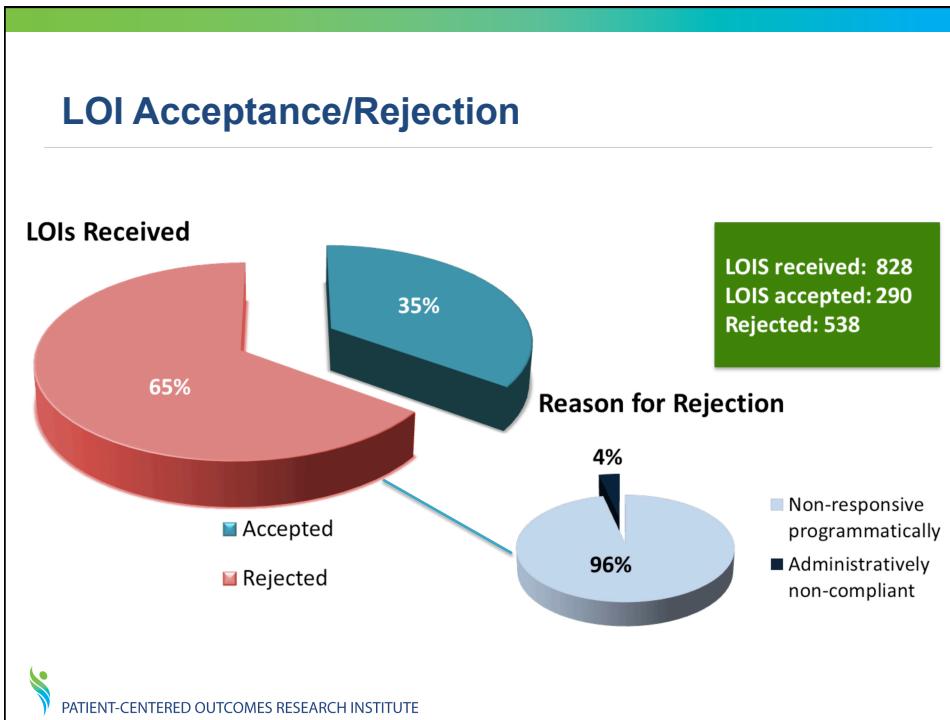
- Letters of Intent are reviewed based on criteria detailed in each PFA
- Additional screening for
 - Comparative effectiveness research
 - Inclusion of cost-effectiveness analysis
 - Administrative responsiveness
- Only responsive LOIs will be invited to submit a full application
- Based on the topic areas of the received LOIs, reviewer recruitment will begin



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PCORI's Online Application Process



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PCORI Online: Application

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



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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



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Project Information

Technical Abstract

Public Abstract

Project Narratives

NOTE

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



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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



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Milestone & Deliverable Schedule



What is the purpose?

NOTE:

How does it differ from the project plan and timeline?

Make it clear that you can achieve your milestones and submit your deliverables in the approved timeframe and within budget.

What information should be included?

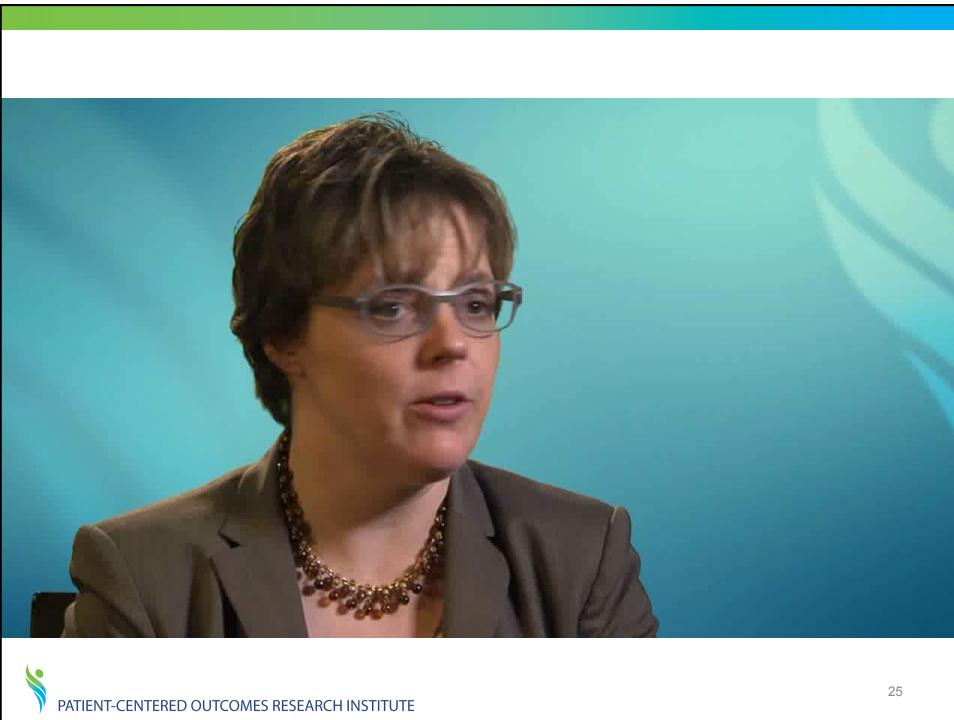
Refer to guidelines for example milestones.

Where should milestones be entered?



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Resubmission Letter



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Resubmission Letter

- Starting this spring there is a new resubmission policy
 - Resubmission may be requested by PCORI
- Review and address the previous reviewers' comments thoroughly



NOTE

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



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What Constitutes a Resubmission?

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



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Research Plan Template



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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

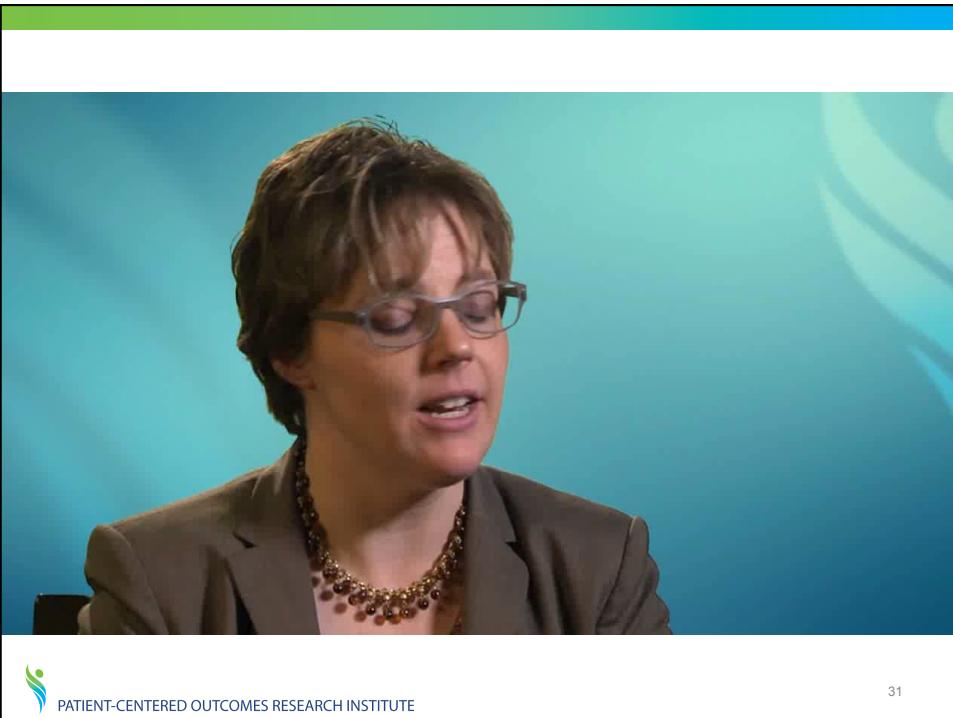
NOTE:

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



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Research Plan Template

- **Research Strategy**
- **Dissemination & Implementation Potential**
- **Replication & Reproducibility of Research and Data Sharing**
- **Protection of Human Subjects**
- **Consortium Contractual Arrangements**
- **References Cited**
- **Appendix**



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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

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NOTE:

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



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Justification of Assumptions

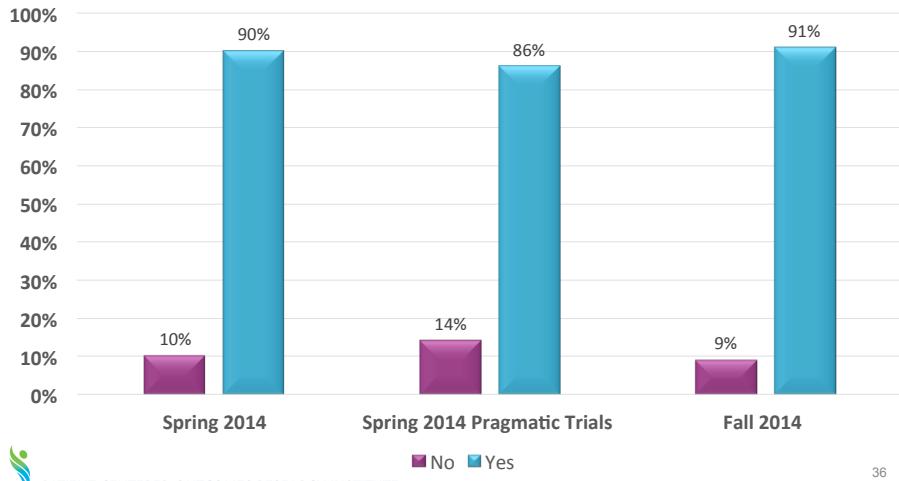
- PCORI seeks studies that are powered to detect meaningful effects.
- Applicants must justify the proposed sample sizes by explaining assumptions used in all study power calculations.
- All estimates must be justified by referring to prior published research or preliminary data.



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Notes on Engagement... Established Partnership Prior to Application



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Dissemination & Implementation



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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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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



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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

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(each)

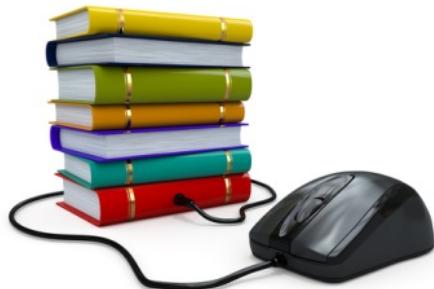


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References Cited

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



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10

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Appendix

Page
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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



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People & Places Templates



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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.



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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

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Professional
Profile/Biosketch

Patient/Stakeholder
Partner Biosketch

Project/Performance
Site(s) and
Resources

NOTE:

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



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Budget



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Budget

- Be reasonable
- Be detailed
- Justify your costs



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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.

Justifying Commonly Denied Items

DENIED

You must do the following:

- Provide a detailed explanation for why the purchase of the requested item(s) is required for project completion.
- Include a statement verifying the requested item(s) is not currently available for PI use.
- Include a statement that the requested item(s) will be purchased in accordance to applicable cost principles.



Items purchased under PCORI funded projects are not to be used as incentives to recruit or retain graduate students or other personnel.



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Budget Templates: Overview

Three budget sections must be submitted as part of the online application process:



A detailed budget is needed for each year of the program. Complete each budget section for the prime applicant and any/each subcontractor.



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Detailed Budget

- Personnel (cap on salary)
- Travel (cap on scientific travel)
- Supply
- Equipment
- Consultant
- Consortium/Contractor
- Other Direct
- Total Direct
- Indirect (indirect cost cap)



NOTES

A detailed budget is needed from each collaborator.
Inpatient and Outpatient Costs within the Detailed Budget
for Each Year of Project Period section has been removed.



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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.



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Budget Summary

- Personnel
- Consultant Costs
- Equipment
- Supplies
- Travel
- Other Expenses
- Consortium/Contractual Direct Costs
- Consortium/Contractual Indirect Costs
- Prime Indirect Costs



A budget summary is required from each collaborator.

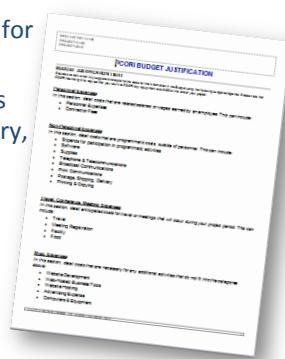


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Budget Justification

- Narrative that fully supports and explains the basis for the information in the Budget Detail
 - Provide sufficient detail to understand the basis for costs, the reason that the costs are necessary, and an explanation for major cost variances
 - Use the budget template to tell PCORI why the costs are reasonable for the work to be performed
- Breakdown of costs proposed for each consortia or contractor
- Must specify any other sources of funding that are anticipated to support the proposed research project
- **Provide quotes, indirect cost rate letter, fringe benefit policy**



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Letters of Support



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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



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PCORI's Online Application Process



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Administrative Requirements

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

Application Checklist		
Section	Description	Submission Method
Letter of Intent	<ul style="list-style-type: none">• Letter of Intent Information• Technical Abstract• Greater Than Emergency Request	<ul style="list-style-type: none">Enter into PCORI Online SystemEnter into PCORI Online SystemUpload as PDF into PCORI Online System
Application	<ul style="list-style-type: none">• PI and Contact Information• Project Information<ul style="list-style-type: none">• Technical Abstract• Project Narratives• Public Abstract	<ul style="list-style-type: none">Enter into PCORI Online SystemEnter into PCORI Online System as part of the Letter of Intent if it is includedEnter into PCORI Online System as part of the Letter of Intent if it is included
Key Personnel	<ul style="list-style-type: none">• Key Personnel	Enter into PCORI Online System
Milestones	<ul style="list-style-type: none">• Milestones	As needed
Research Plan	<ul style="list-style-type: none">• Research Plan (if appropriate)<ul style="list-style-type: none">• Research Strategy• Dissemination and Implementation• Potential• Feasibility and Comparisons• Research• Protection of Human Subjects• References Cited• Consortium Contractual Arrangements• Appendix (optional)	<ul style="list-style-type: none">Enter into PCORI Online SystemEnter into PCORI Online SystemAs noted below
Engagement Template	<ul style="list-style-type: none">• Engagement Template (if applicable)	<ul style="list-style-type: none">Save as "Engagement_Pi_Last Name.pdf" and upload4 pages

NOTE:

Applications that do not meet the formatting criteria or documentation requirements may be eliminated from consideration.



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PCORI's Online Application Process



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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**



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But Wait....

What if I Miss the Deadline??



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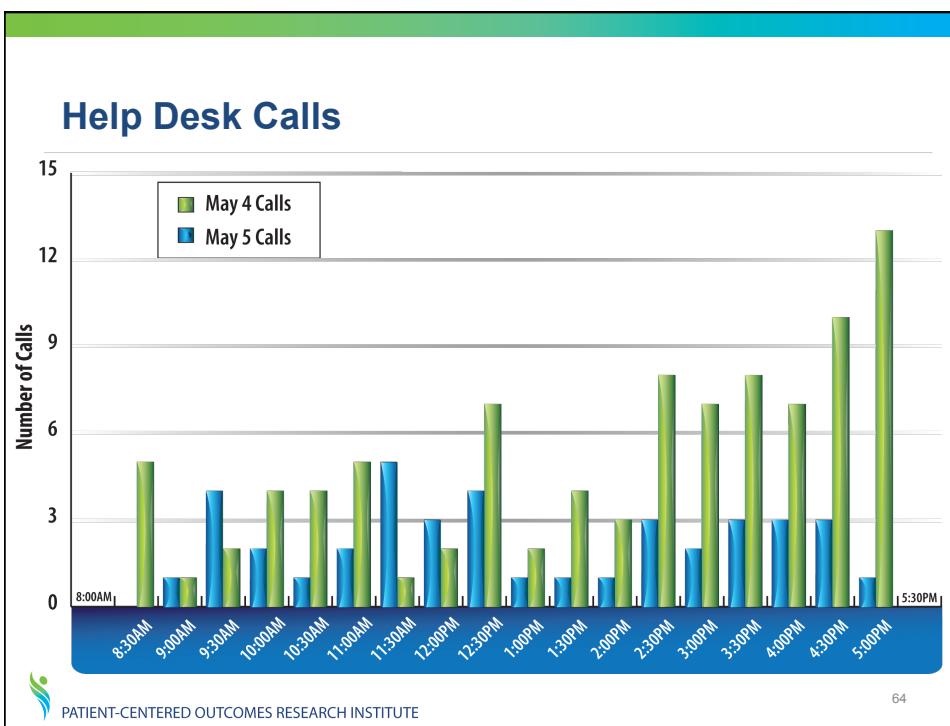
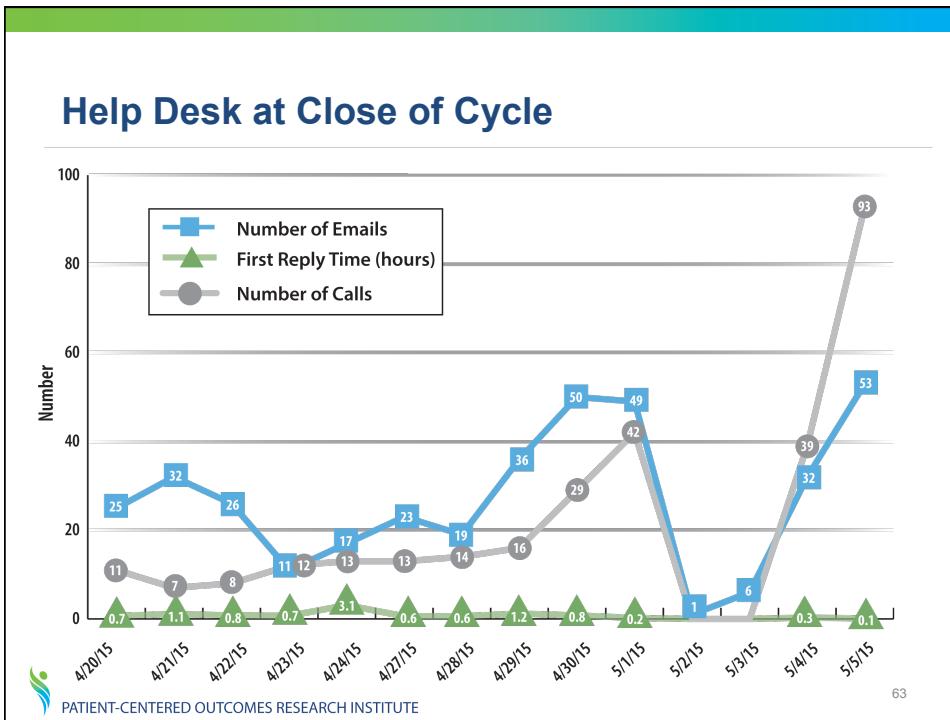
PCORI Help Center



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

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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

[APPLY NOW](#)

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.

[APPLY NOW](#)

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What Happens Next? PCORI's Merit Review Process

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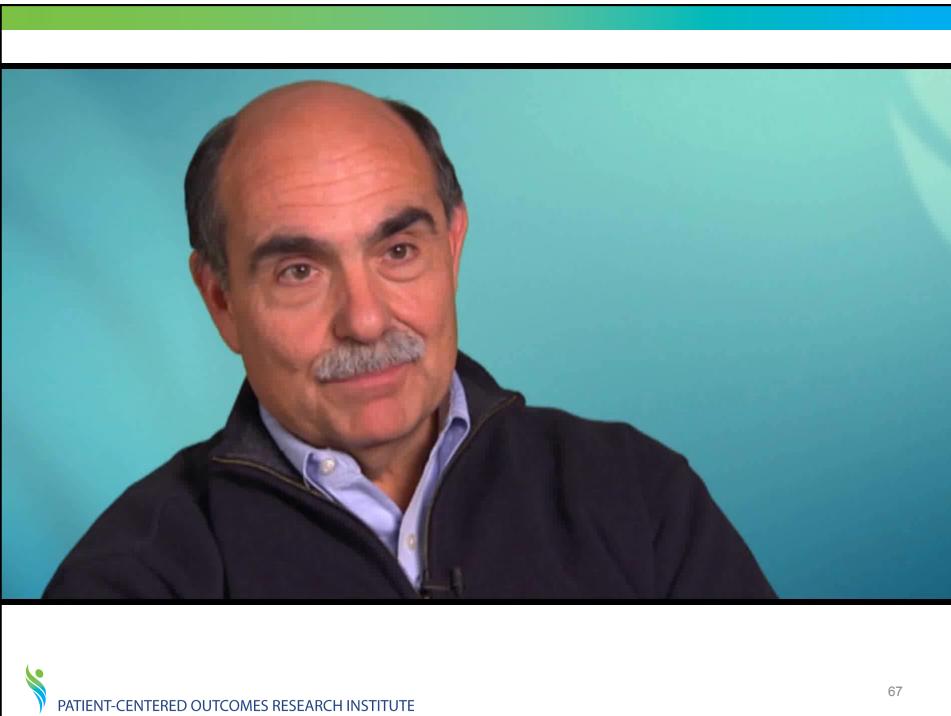


~5 Months

Application Deadline Final Decision

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Administrative Screening

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



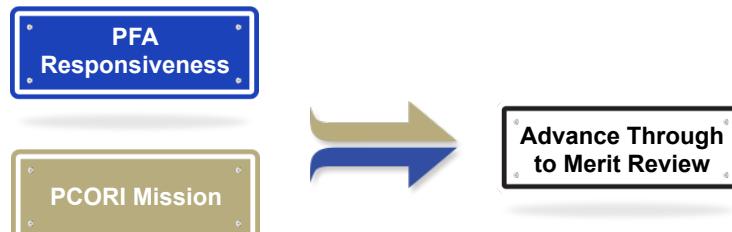
- ▶ Exceeding page limits, budget, or time limitations
- ▶ Not using PCORI's required templates
- ▶ Submitting incomplete sections or applications
- ▶ Modifying margins or font size



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Programmatic Screening



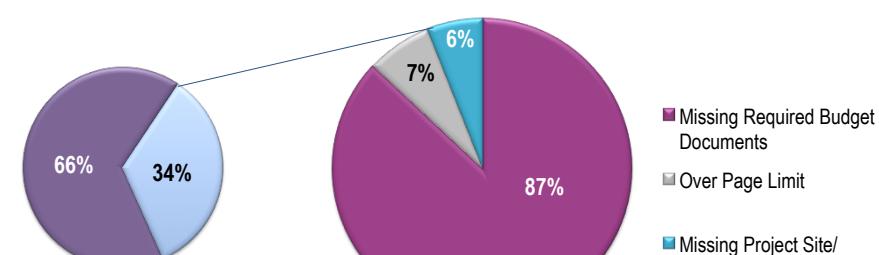
- ▶ Study deviates from approved LOI
- ▶ Study includes cost-effectiveness analysis
- ▶ Study is not responsive to PFA and/or does NOT address the PFA's "Research Areas of Interest"
- ▶ Study is not comparative



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Applications Screening Statistics



■ Number of Applications Received Without Issues

■ Number of Applications Received With Issues

■ Missing Required Budget Documents

■ Over Page Limit

■ Missing Project Site/Resources



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Merit Review



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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 2 scientists, 1 patient, and 1 other stakeholder.
- Chair facilitates discussion and promotes a culture of mutual respect and understanding among reviewer types



Patients



Scientists



Other Stakeholders



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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	✓	✓

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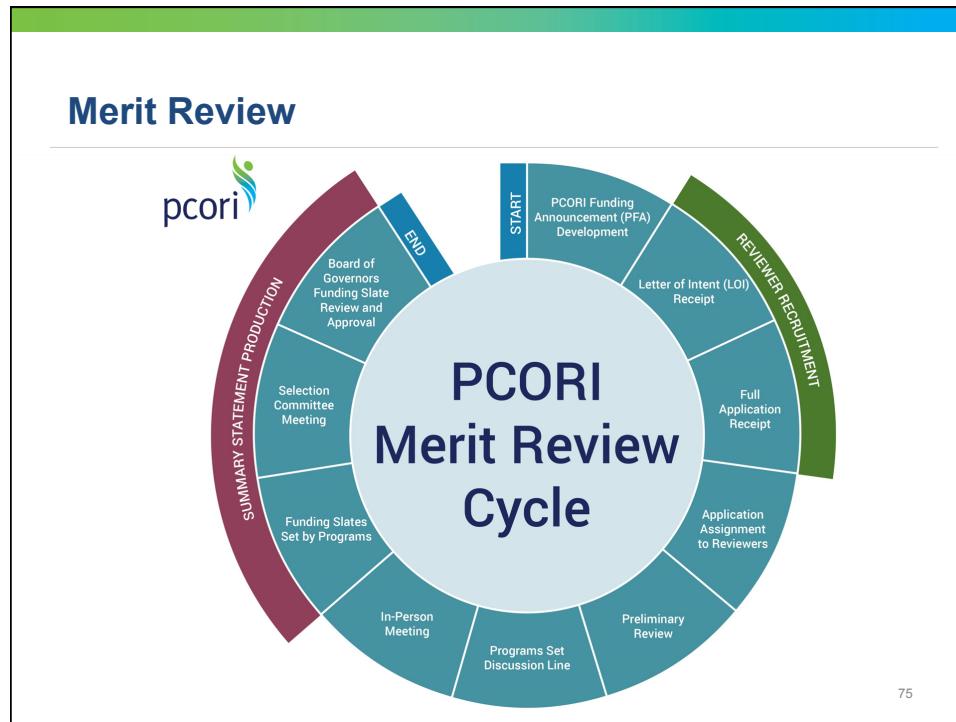
Scoring Range			
Range	Score	Descriptor	Characteristics
High	1	Exceptional	Exceptionally strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor weaknesses
Medium	4	Very Good	Strong but with numerous minor weaknesses
	5	Good	Strong but with at least one moderate weakness
	6	Satisfactory	Some strengths but also some moderate weaknesses
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 1 indicates an exceptionally strong application.

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

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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



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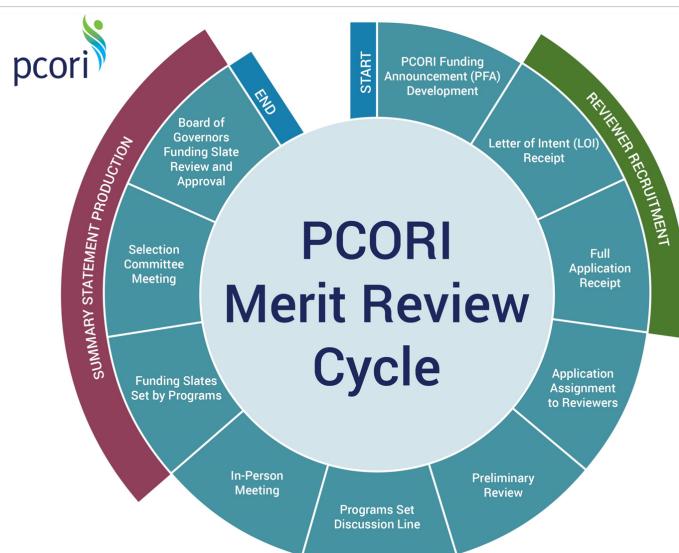
PCORI Information Request (PIR)

- 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.**



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Merit Review



Become a Reviewer

- PCORI review panels include scientists, patients, and other stakeholders to bring diverse perspectives to the review process.
- We continue to welcome applications to become a reviewer in all categories.



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How to Apply to be a PCORI Reviewer

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Thank You!

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