

The PCORI Application Process

James Hulbert
Pre-Award Manager

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Welcome!



James Hulbert
Pre-Award Manager



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Session Objectives

- 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
- Introduce the review process
- Discuss the PCORI information request process
- Describe where to find help



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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



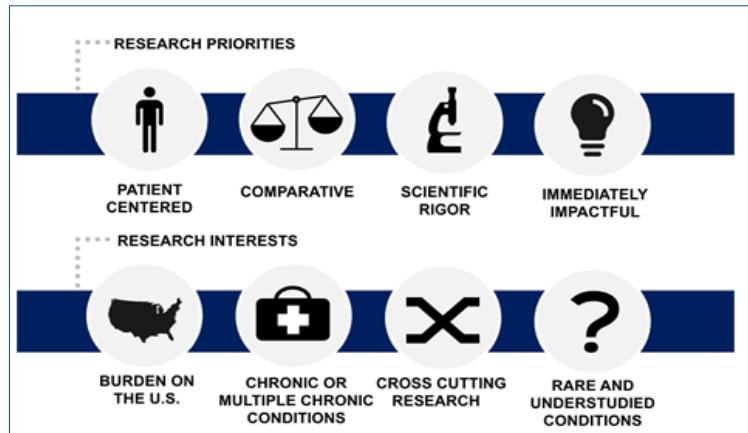
NOTE
PI must be an employee of the prime applicant institution. Individuals are not eligible to submit research applications to PCORI.



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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

BLOG CAREERS NEWSROOM SUBSCRIBE CONTACT

pcori Patient-Centered Outcomes Research Institute

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

Documentation of Assumptions has been renamed
Justification of Assumptions and moved to the
Application Guidelines.

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PCORI's Online Application System

Login No.
Username
Password
Sign in
Reset

Come visit the Help Desk while you are in Houston!

or

PCORI new create

password" link to the left to receive your new password.

NOTE

There are new LOI Template prescreen questions in the PCORI online 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



Be sure to use the correct LOI template for the current cycle and PFA.



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Responsiveness Review

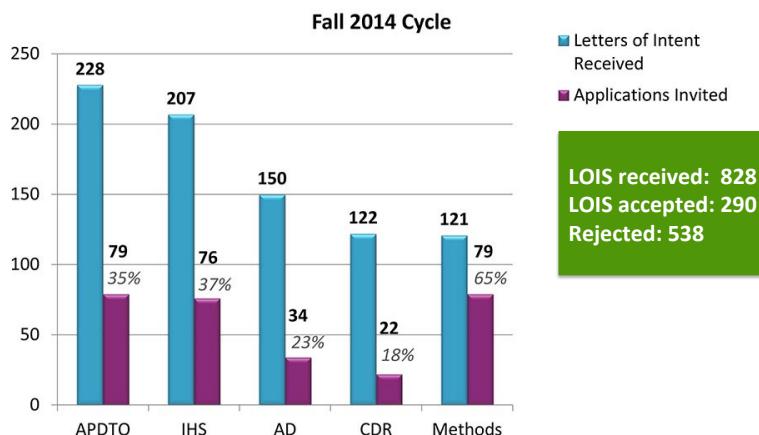
- Letters of Intent are reviewed based on criteria detailed in each PFA
- Additional screening for
 - Comparative effectiveness research
 - Inclusion of cost-effectiveness analysis
 - Administrative Guidelines
- Only responsive LOIs will be invited to submit a full application
- Based on the topic areas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



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Fall Cycle LOIs



APDTO = Assessment, Prevention, Diagnosis and Treatment Options

IHS = Improving Healthcare Systems

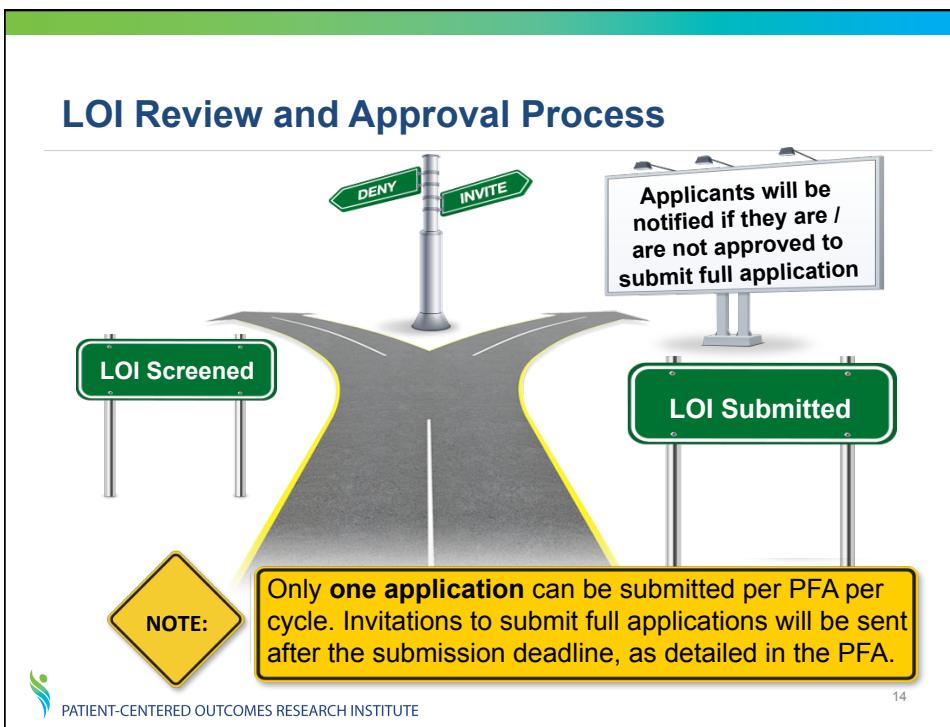
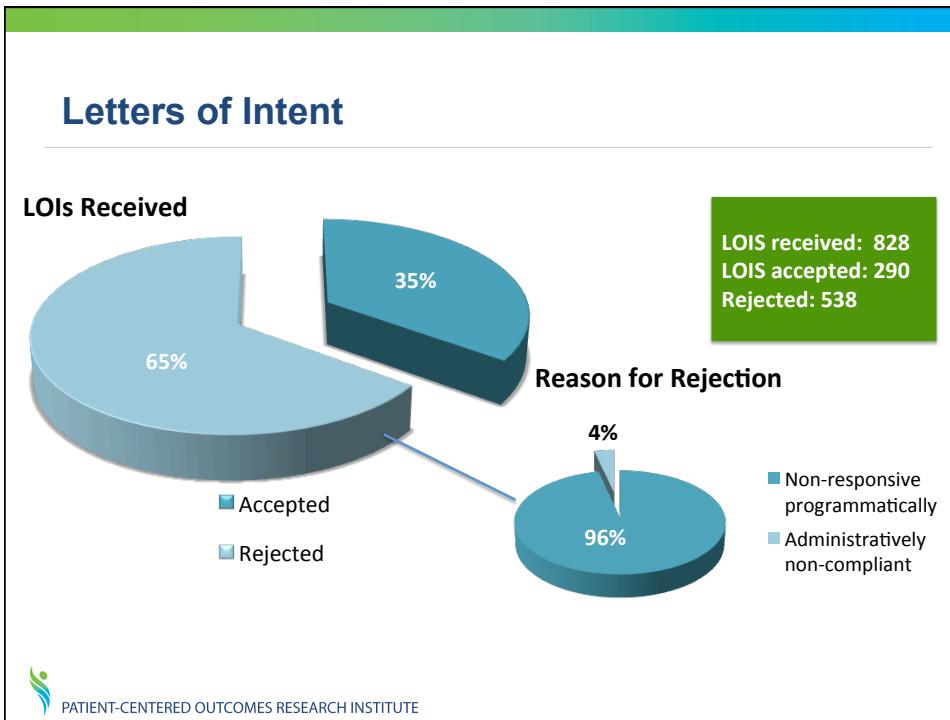
AD = Addressing Disparities

CDR = Communication and Dissemination Research

Methods = Improving Methods for Conducting Patient-Centered Outcomes Research



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Greater than Time/Budget Request: Budget Limitations

As of 2015, PCORI is no longer accepting Greater Than Budget and Time Requests for Broad PFAs



NOTE:

Do not expect to receive either a cost or a no-cost extension.



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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 in
Engagement



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Project Information

Technical Abstract

Public Abstract

Project Narratives

NOTE

Research Strategy instructions in the Research Template and Application Guidelines have been updated.

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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?

How does it differ from the project plan and timeline?

What information should be included?

Where should milestones be entered?

NOTE:

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

Refer to guidelines for example milestones.



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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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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

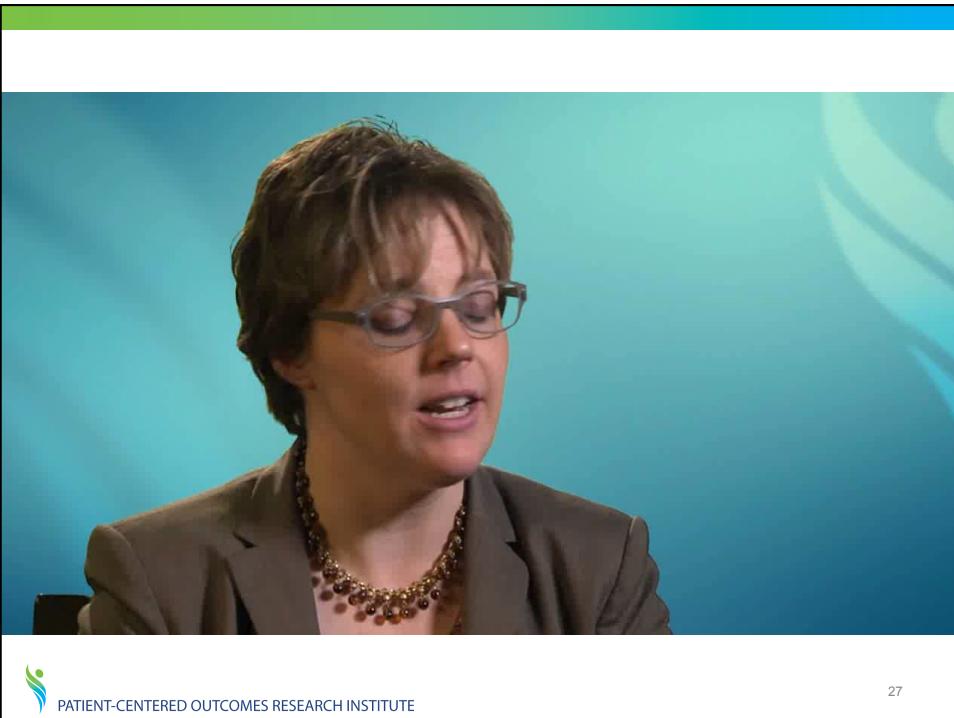
NOTE:

The Research Plan must be submitted as one PDF file with all sections completed, as applicable.



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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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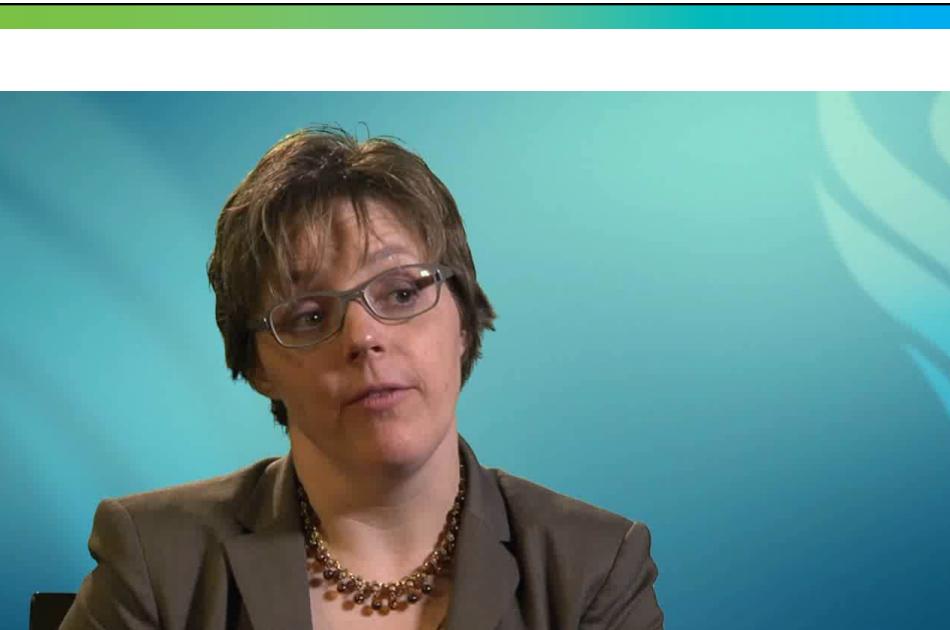
NOTE:

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



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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.

Protection of Human Subjects

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

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(each)

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

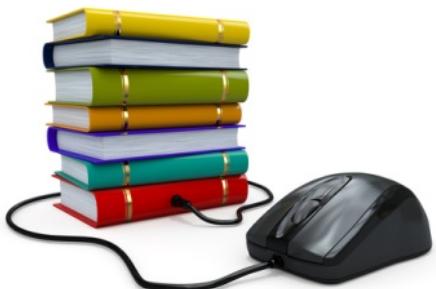


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References Cited

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



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Appendix

- 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

NOTE:

Build an appropriate and well-justified research team who can provide assurance the project will be successful.

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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

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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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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	No
Addressing Disparities	\$8 Million	\$1,500,000	3 Years	No
Improving PCOR Methods	\$12 Million	\$750,000	3 Years	No
Large Pragmatic Studies	\$90 Million	\$10,000,000	5 Years	Yes (budget)



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Budget

- Be reasonable
- Be detailed
- Justify your costs



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Allowable and Unallowable Costs

PERSONNEL SALARIES & BENEFITS	CONSULTANT FEES	TRAVEL COST	ADVERTISING	DONATIONS	INTEREST OF BAD DEBTS	ALCOHOLIC BEVERAGES
EQUIPMENT		SUBCONTRACTOR DIRECT & INDIRECT	EXCESSIVE AIRFARE	FUNDRAISING	ENTERTAINMENT	PERSONAL EXPENSES
SUPPLIES	OTHER	APPLICANT INDIRECT COST	LOSSES ON OTHER GRANTS	ALUMNI ACTIVITIES	STUDENT HOUSING STIPENDS	MEMBERSHIP
			BAD DEBTS AND/OR LOSSES	IDLE FACILITIES	LOBBYING	INPATIENT & OUTPATIENT COST

Allowable Cost

Unallowable Cost

NOTE

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

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Detailed Budget

- Personnel
- Travel
- Supply
- Equipment
- Consultant
- Consortium/Contractor
- Other Direct
- Total Direct
- Indirect



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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Budget Summary

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

NOTE:

A budget summary is required from each collaborator.



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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



NOTE:

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



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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**

A screenshot of the PCORI Budget Justification form. The form includes sections for "Project Overview", "Budget Justification", "Non-Direct Costs", "Other Costs", and "Total Budget". It contains various input fields for financial information and descriptions of the research project.

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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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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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Administrative Requirements

- Include but are not limited to:
 - Required Templates
 - Length/Limit
 - File Formats
 - File Naming Conventions

Application Checklist			
	Letter of Intent	Submission Method	Length/limit
<input type="checkbox"/>	<ul style="list-style-type: none"> ▪ Letter of Intent ▪ Project Identification ▪ Technical Abstract ▪ Greater Than One Page Request 	<ul style="list-style-type: none"> Enter into PCORI Online System Enter into PCORI Online System Upload as PDF file into PCORI Online System 	<ul style="list-style-type: none"> N/A 6,000 characters/spaces As noted
<input type="checkbox"/>	Application	Enter into PCORI Online System	10 pages
<input type="checkbox"/>	Pi and Contact Information	Enter into PCORI Online System and add if needed	N/A
<input type="checkbox"/>	Project Information	<ul style="list-style-type: none"> ▪ Technical Abstract ▪ Project Narrative ▪ Public Abstract 	<ul style="list-style-type: none"> Enter into PCORI Online System and modify if needed. Enter into PCORI Online System and modify if needed. Enter into PCORI Online System and modify if needed.
<input type="checkbox"/>	Key Personnel	Enter into PCORI Online System	3,000 characters/spaces
<input type="checkbox"/>	Milestones	Enter into PCORI Online System	As needed
<input type="checkbox"/>	Research Description	<ul style="list-style-type: none"> ▪ Researcher(s) (if appropriate) ▪ Research Strategy ▪ Potential and Impact ▪ Reproducibility of Approach ▪ Protection of Human ▪ References Cited ▪ Consortium Contractual Arrangements ▪ Appendix (optional) 	<ul style="list-style-type: none"> Save file as "Researcher(s)_Last Name.pdf"
<input type="checkbox"/>	Engagement Template	Save as "Engagement_Pi Last Name.pdf" and upload	4 pages



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

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Tips for Success

- Download [PCORI's Online User Manual for Submitting an Online Application](#)
- Adhere to the PFA and Application Guidelines for the **funding cycle you are applying to**
- Ensure that all team members can see the application in the system (check during the LOI stage)
- Submit the completed application before the due date or on it by **5:00 PM ET**



PCORI's Online Application is NOT like Grants.gov.
Familiarize yourself with the system and start the application process early.



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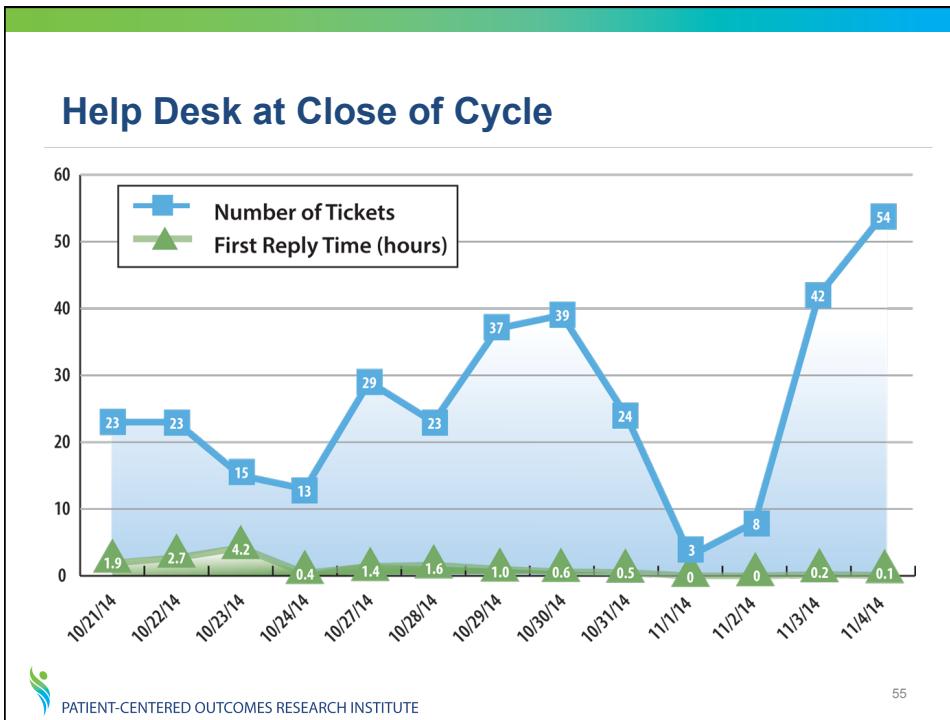
But Wait....

What if I Miss the Deadline??



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PCORI Help Center

APPLICANT RESOURCES
REVIEWER RESOURCES
ENGAGEMENT AWARDS

ASK A QUESTION
CHECK EXISTING QUESTIONS

Applicant Resources

Find Help Center answers

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.

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

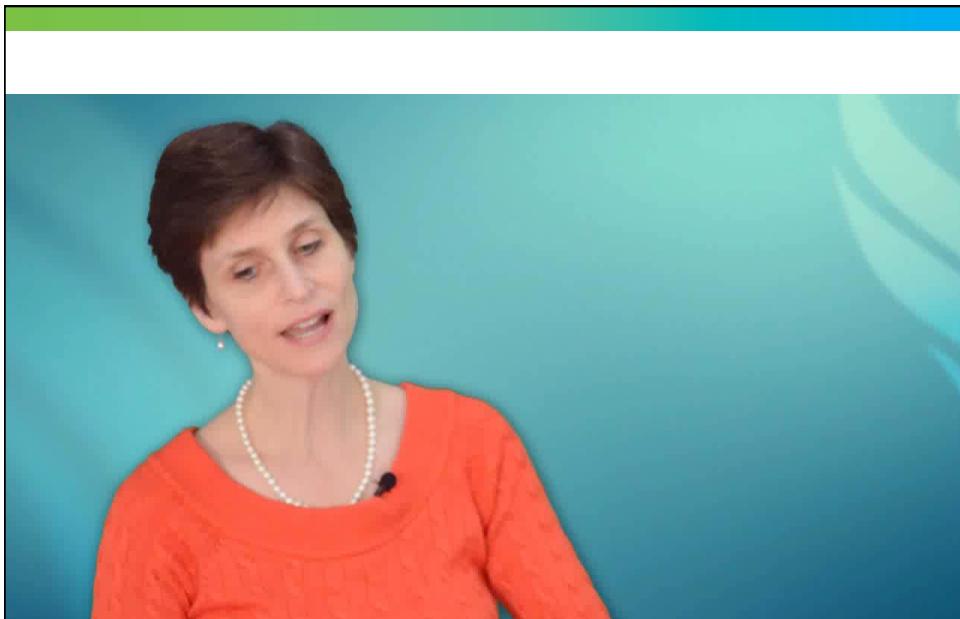
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What Happens Next? PCORI's Merit Review Process



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Programmatic Screening

PFA
Responsiveness

PCORI Mission



Advance Through
to Merit Review



- ▶ 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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Administrative Screening

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

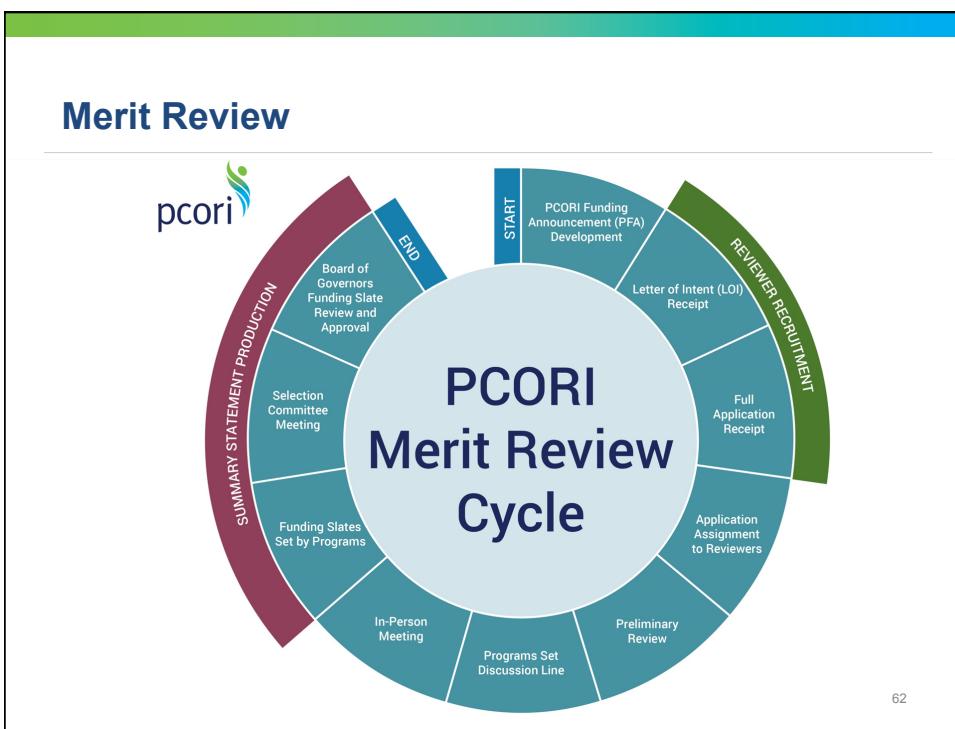
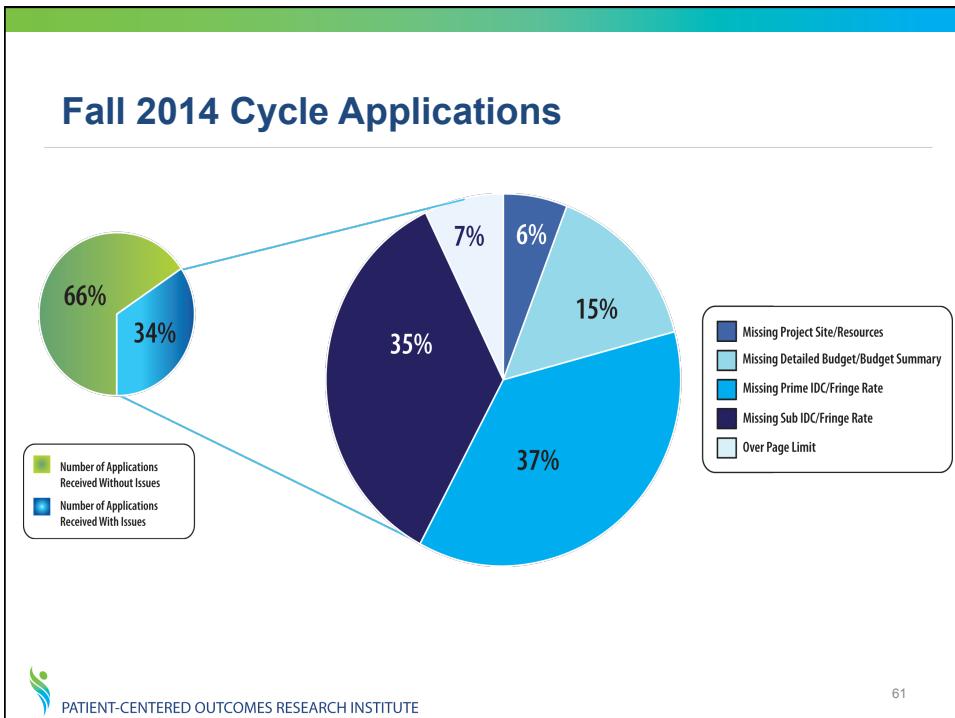


- ▶ Exceeding page limits, budget, or time limitations
- ▶ Not using PCORI's required templates
- ▶ Submitting incomplete sections or applications



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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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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.



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Summary

- Sections of the PCORI application
- Purpose of each template in the PCORI Application Process
- Where to find help



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Questions?

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Thank You!

James Hulbert
Pre-Award Manager



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